CASE STUDY

Implementing a critical infectious disease protocol

Overcoming enrollment challenges in a complex ICU trial

Enrolling critically ill patients in clinical trials presents unique challenges. A major global pharmaceutical company recently faced this scenario while testing a novel treatment for severe infections in intensive care units. The Phase I trial required the recruitment of mechanically ventilated patients across 18 sites in six countries, spanning North America, Europe and Asia-Pacific.

To navigate these complexities, the pharmaceutical company partnered with Fortrea. Our Global Product Development and Clinical Operations teams worked closely with the sponsor and site investigators to develop and implement strategies that would respect the sensitive nature of ICU research while meeting the study's goals.

The challenge: navigating complex ICU research

This trial included several complex obstacles:

- Ethical considerations and consent process for mechanically ventilated patients with no expected benefit from participation
- Integration of study procedures with existing ICU protocols and workflows
- 24/7 recruitment and study procedures demanding flexible staffing solutions
- Drug delays and customs issues in the Asia-Pacific region
- Data management and query issues leading to site fatigue

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Early engagement and tailored solutions

To address these challenges, we implemented a proactive strategy focused on early engagement and customized approaches. We initiated discussions with principal investigators (PIs) during the feasibility stage and throughout protocol finalization, gathering crucial insights to refine the protocol based on real-world ICU experiences. Recognizing each site's unique characteristics, we developed tailored patient identification and recruitment strategies aligning with their specific ICU environments.

Facilitating collaborative sessions between PIs, our medical experts and the sponsor's clinical science group fostered open dialogue. Throughout the study, we provided comprehensive support to sites, including dedicated assistance with complex procedures and ongoing communication to address emerging issues promptly.

To overcome supply chain challenges, we worked closely with local regulatory experts and logistics partners to expedite processes while ensuring compliance. We monitored site activation progress closely, reallocating resources as needed to support sites facing delays and maintain steady patient enrollment. Addressing site fatigue, we implemented a streamlined query resolution process and provided additional support through our clinical team leads (CTLs) and clinical research associates (CRAs).

Study execution

Through close collaboration with ICU teams and site-specific recruitment strategies, enrollment progressed more rapidly than anticipated. Even as a fourth cohort was added to the original three, milestones were consistently completed on time or ahead of schedule.

Key results of the study included:

- Enrollment completed 9 months ahead of schedule for cohorts 1-3
- Additional cohort 4 enrolled in under 4 months
- 47 patients enrolled vs 27 originally planned

These outcomes provided the sponsor with a larger sample size and more robust data, while maintaining efficiency in study closeout and reporting.

Lessons learned for ICU clinical trials

This complex ICU trial yielded valuable insights that can inform future critical care research. Early engagement with principal investigators during the feasibility stage and protocol development proved crucial, allowing for refinements that balanced scientific rigor with practical ICU considerations. Recognizing each ICU's unique characteristics and developing site-specific patient pathways significantly improved recruitment efficiency.

Clear communication channels between all stakeholders facilitated rapid problem-solving and ensured alignment throughout the study. Regular tripartite meetings and ongoing dialogue contributed to the overall success. The team's adaptability and commitment to core principles fostered trust with both the sponsor and sites, creating a collaborative environment that drove the study forward.

Conclusion

The successful execution of this complex ICU trial demonstrates the critical role of collaboration, expertise and adaptability in advancing infectious disease trials. At Fortrea, we are committed to supporting innovative research in critical care and beyond. By continuously refining our approaches and embracing the complexities of cutting-edge clinical trials, we aim to contribute to the advancement of treatments that can make a significant difference in patients' lives.

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