See how we navigated complexities in a Phase I ICU trial

Recent years have seen a growing need for advanced critical care solutions, driven by factors such as an aging population, emerging infectious diseases and increasingly complex medical interventions. ICU research is crucial for developing innovative treatments that can improve outcomes for the most vulnerable patients. However, conducting research in this environment presents a unique set of obstacles.

A recent Phase I trial provides insights into these challenges and potential solutions. The study, conducted by a major global pharmaceutical company in partnership with Fortrea, tested a novel treatment for severe infections in mechanically ventilated ICU patients.

Understanding the ICU research landscape

ICUs deal with the most severe and life-threatening conditions, where timely interventions can significantly impact patient outcomes. From sepsis and acute respiratory distress syndrome (ARDS) to multi-organ failure, the complexity of conditions treated in the ICU demands constant innovation in therapeutic approaches.

One of the most significant challenges in ICU research is navigating the ethical landscape. Many ICU patients are unconscious or too ill to provide informed consent, raising complex considerations for patient autonomy and the role of surrogate decision-makers. Researchers must carefully balance advancing medical knowledge with protecting vulnerable patients, often under time-sensitive conditions.

The ICU environment also creates the need for 24/7 operations, integration of study protocols with urgent care, rapid decision-making, complex data collection, high staff workload and equipment and space constraints. ICUs function round-the-clock, requiring study protocols that can be implemented at any time. Study procedures must be seamlessly integrated with ongoing critical care, without compromising patient safety or treatment efficacy.

The dynamic nature of critical illness means that decisions about patient eligibility and study interventions often need to be made quickly, with limited time for deliberation. Additionally, the wealth of data generated in ICU settings, from continuous vital sign monitoring to frequent lab tests, presents both opportunities and challenges for researchers. ICU staff are often already working at capacity, making it challenging to add the additional responsibilities of a clinical trial. Moreover, ICUs are typically crowded environments with limited space for additional study-related equipment or personnel.

Fortrea

Strategies for success in ICU trials

Given the unique challenges of ICU research, implementing effective strategies is crucial for trial success.

The Phase I trial conducted by the global pharmaceutical company and Fortrea employed several key approaches:

- **Early engagement with principal investigators** proved invaluable. By involving PIs during the feasibility stage and throughout protocol finalization, the team gathered crucial insights to refine the study design based on real-world ICU experiences. This early collaboration helped anticipate and address potential issues before they could impact the trial
- **Tailored site-specific approaches** were developed to align with each ICU's unique characteristics. Recognizing that no two intensive care units operate identically, the team created customized patient identification and recruitment strategies for each site. This flexibility allowed for more efficient integration of study procedures with existing ICU protocols and workflows
- **Flexible staffing solutions** addressed the demands of 24/7 recruitment and study procedures. The team implemented creative scheduling and on-call systems to ensure that qualified personnel were available at all hours, minimizing disruptions to both the study and routine ICU operations
- **Proactive supply chain management** was crucial, especially in regions prone to customs delays. By working closely with local regulatory experts and logistics partners, the team expedited processes while ensuring compliance, preventing potential delays in drug availability
- To **reduce site fatigue,** streamlined data processes were implemented. This included optimizing the query resolution process and providing additional support through clinical team leads (CTLs) and clinical research associates (CRAs). By minimizing the administrative burden on already-stretched ICU staff, the team maintained high-quality data collection without overwhelming site personnel

The power of collaboration

The success of ICU trials often hinges on strong partnerships between all stakeholders. This study exemplified the power of effective collaboration, enabling rapid problem-solving and maintained commitment from all parties throughout the study's duration. By establishing clear lines of dialogue between sites, sponsors and hospital staff, issues were quickly identified and resolved. This transparency not only built trust but also kept all stakeholders informed and engaged, creating a dynamic and responsive research environment. Perhaps most critically, the study leveraged diverse expertise to tackle the unique challenges of ICU research. By combining the sponsor's clinical knowledge, Fortrea's operational experience and the sites' practical ICU expertise, the team developed solutions to emerging challenges.



Measuring trial success

Several key metrics were used to measure the trial's success:

- Enrollment metrics and timelines are critical indicators. In this case, the study team exceeded expectations. Enrollment for the first three cohorts was completed nine months ahead of schedule, allowing for the addition of a fourth cohort. This additional cohort was enrolled in under four months, further demonstrating the efficiency of the team's approach
- Data quality and integrity are paramount in any clinical trial, but especially so in the complex ICU environment. Despite the challenges of collecting data in a critical care setting, the team maintained high standards of data quality. This was achieved through careful training of site staff, regular monitoring and the implementation of streamlined data management processes
- Stakeholder satisfaction provides valuable insights into the overall success of a trial. Feedback from investigators, site staff and the sponsor team indicated high levels of satisfaction with the study's conduct. The collaborative approach and responsive problem-solving were particularly noted as strengths

The success of this trial, as evidenced by these metrics, demonstrates the potential for overcoming the unique challenges of ICU research. By employing targeted strategies, fostering strong collaborations and maintaining a focus on key performance indicators, it is possible to conduct efficient and high-quality clinical trials in even the most complex critical care settings.

Explore our approach

The landscape of ICU research, while challenging, offers immense potential for advancing critical care medicine. This Phase I trial for a novel treatment in mechanically ventilated patients illuminates several key lessons for conducting successful ICU clinical trials.

For a deeper dive into this Phase I ICU trial, download the full case study.

LEARN MORE at fortrea.com

Fortrea

©2024 Fortrea Inc. All Rights Reserved.
IS_0071_PK ICU_0924