INFECTIOUS DISEASE CASE STUDY

Creative problem-solving supports site recruitment in a complex sepsis study.

A drug development sponsor sought Fortrea's support to run their global Phase III study involving patients with septic shock. This case study shares best practices for site recruitment support in an intensive care unit (ICU) and describes how the team initiated the study and worked to overcome challenges associated with conducting clinical research in this setting.

Understanding the challenges

Given that ICU sites are inherently busy, running a successful study requires supporting site staff to help them recruit sepsis patients quickly and conduct the study with quality and patient safety. These sites were also under unprecedented pressure, as this study occurred during the pandemic, creating additional challenges for operationalizing this study. Furthermore, this septic shock study had a complex study protocol, including an intense ICU-based treatment period and long-term follow-up with approximately 1,550 subjects across 130 sites in 15 countries spanning the EU, US and APAC.

Developing and deploying targeted solutions

Fortrea first assembled a highly experienced core project team along with functional experts to support the sponsor. This team already had very strong relationships with the sites and worked to forge equally close collaborations with all stakeholders in the study.

To support enrollment, Fortrea created flexible regional and site-specific strategies that focused on site- and patient-centricity. Throughout the engagement, they developed processes and generated insightful reports that helped monitor site performance, operations and data collection and ensured the study remained on track.

KEY TAKEAWAYS

Fortrea demonstrated flexibility to support recruitment for this complex, ICU-based study by:

- Developing site- and patient-centric strategies that supported enrollment
- Streamlining site processes with a comprehensive study portal
- Creating patient-friendly materials that reduced the burden on site staff

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Best practices for streamlining site processes to drive recruitment

Fortrea recognized the need to streamline site processes and created a study portal as a "one-stop shop." This portal included all training, site reference materials/systems and patient pre-screening forms. More than 5,000 patient-related forms were submitted through this well-used portal, which also included audit-ready training modules to support any transitions of site staff.

Fortrea also gave each site a "grab bag" that contained all study documentation needed to review and consent a patient. Beyond the informed consent form (ICF), pre-screening, screening and enrollment checklists, the grab bag materials included education materials for patients and/or family members to better understand the study. These patient-friendly materials were designed to answer common questions, which helped the busy ICU staff focus on running tests and reduced some of the burden associated with screening and enrollment.

Based on the initial success observed with these materials, many sites asked Fortrea for additional copies of the materials and even suggested additional patient-facing tools throughout the duration of the trial.

Recognizing the value of supporting patients and site staff

Despite challenges related to COVID-19, the target recruitment rate was achieved. The sponsor was pleased that interim analysis and the database lock (DBL) were delivered on time with 0% data loss for the primary endpoint.

Studying the complications of septic shock requires navigating the complexities of a clinical trial while incorporating the needs of patients and ICU site staff. The Fortrea team demonstrated their commitment to supporting each site and ultimately helped the sponsor make a difference in their ongoing pursuit to bring new treatments to critically ill patients.

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