CASE STUDY

Creating site and patient centric solutions for a challenging antibiotic pharmacokinetic (PK) study

A KEY QUESTION

How did Fortrea help sponsors and sites with protocol design in a PK study?

KEYWORDS Pharmacokinetic, Antibiotic, Nosocomial Infection, ICU Setting, Investigator Engagement, Protocol Optimization

A pharmaceutical company partnered with Fortrea to support their Phase Ib pharmacokinetic clinical trial of a new antibiotic candidate for life-threatening nosocomial infections, including drug-resistant infections. While this study was not expected to be beneficial to enrolled patients, it would advance science, inform future clinical research and help close gaps in understanding to address future unmet medical needs in patients with life-threatening infections.

Recognizing the challenges

Based on standard feasibility surveys, the sponsor was not confident that physicians would be willing or effective in participating in the study. The sponsor needed Fortrea's support to gather investigator-specific feedback and gauge the ability to perform this study, which involved:

- A single-dose pharmacokinetic (PK) study in an intensive care unit (ICU) setting
- No expected benefit for the participant
- Consent from a legally authorized representative (LAR) for most patients
- Invasive procedures
- Protocol procedures that were not all standard of care (SOC) for these patients

KEY TAKEAWAYS

Fortrea worked closely to support the sponsor and the sites in this pharmacokinetic (PK) study by:

- Identifying interested sites and any potential barriers to their participation
- Facilitating productive medical and operational conversations with principal investigators and implementing a feedback loop to inform the protocol design
- Supporting critical data-driven decision-making that ultimately resulted in a successful Phase Ib PK study

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Evaluating interest and discussing key concerns

To help support the PK study, Fortrea scheduled online meetings in each targeted country. Principal investigators (PIs) that showed the most interest during the site identification process were invited to speak with the sponsor's scientists. These meetings included **Fortrea's project management** team as they worked together to discuss **site-centric solutions** and address any perceived challenges with the sponsor's proposed protocol.

To guide the discussion around the PI's potential concerns about the complexity of the protocol and patient population, Fortrea developed an interview script with the sponsor before each PI feasibility meeting. Immediately after each meeting, Fortrea sent summary slides to the sponsor so they could evaluate important recommendations and make appropriate adjustments to the protocol and discuss the inclusion of the PI for the study.

Incorporating feedback to strengthen the protocol

With these meetings, the sponsor gained investigator-specific information that helped build informed decision-making to support the viability of the PK study. The sponsor then incorporated feedback from the investigators to finalize the protocol. They also gained the confidence of the investigators as the resulting protocol focused on the needs of the sites and patients.

The final protocol was considered ethically sound and more closely resembled SOC treatment for these patients. For example, the PK sampling times were adjusted to allow for increased collection window times and bronchoalveolar lavage (BAL) was updated as an optional procedure in cohorts 1-3; the collection procedure was adjusted to nearly match SOC for cohort 4 in the protocol amendment.

Recognizing the results

As a result of this study, the sponsor and the PK study volunteers contributed to vital scientific knowledge that helps the research community better understand how therapeutic interventions for patients with nosocomial infection in an ICU setting may produce different pharmacokinetics than would be produced by healthy volunteer studies. Supported by the foundation of these initial results, the study continues to progress through clinical development of a new treatment option for these critically ill patients.

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Together, exceptional is possible

Together, we can advance your anti-infective program and creatively manage the challenges of antibacterial clinical trials in an ICU setting. We also can support you in site- and patient- centric protocol design for better outcomes.

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