CASE STUDY

Serving as more than a partner to support a combination antibiotic clinical trial

A large pharmaceutical company was running a complex antibiotic study for a treatment targeting complicated intra-abdominal infection (cIAI). Based on extensive experience with facilitating and executing these complex antibiotic studies, Labcorp Drug Development was selected to support this Phase IIb trial. This case study highlights the team's approach to remove barriers to enrollment and keep the study on schedule.

Performing site feasibility and ensuring rapid enrollment and sample processing

cIAI represents the second most common source of sepsis, which is associated with a significant mortality rate despite current treatment strategies. Recognizing the combined risks associated with cIAI, sepsis and the emergence of multidrug-resistant bacteria, the sponsor wanted to study a new antimicrobial and test the safety, tolerability and efficacy of their treatment in combination with an existing treatment regimen.

The study drug needed to be administered as an intravenous (IV) treatment. The sponsor requested that Labcorp perform thorough site feasibility tasks, which included ensuring that the sites had compatible IV tubing. Getting accurate, timely information about a site's equipment was a labor-intensive process that began to threaten the study startup timeline.

Enrollment of patients also presented its own set of challenges. The sites needed to quickly identify potential patients, which required rigorous screening within 24 hours to ensure no prior antibiotic therapies had been administered. Additionally, informed consent needed to be obtained while most of these patients were unconscious, and the regulations surrounding the enrollment of unconscious study participants varied from one country to another.

For processing of samples, many of the selected sites that were forecasted to efficiently support recruitment efforts did not have in-house facilities to test the isolates collected from patients. Labcorp needed to set up a streamlined system for processing these samples and generating accurate results.

Key Takeaways

- Optimized the study startup timeline with strategic site selection and feasibility efforts
- Examined aggregate data to highlight trends and deviations at a site and global level
- Achieved on-time completion and urgently delivered high-quality data to proceed to Phase III

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Gathering real-time evidence and creating site-specific plans

The sponsor's initial protocol prescribed that all potential facilities needed to be inspected to ensure that their IV tubing was compatible with the study drug. This was a tedious and time-consuming process, and the Labcorp team quickly recognized that site selection could be severely delayed as a result. It was soon observed, however, that 99% of the initial sites inspected did in fact possess the required tubing. The Labcorp team communicated their preliminary findings to the sponsor, who then agreed to remove this time-intensive mandate, which allowed the team to speed up site selection and keep study startup on schedule.

Next, Labcorp worked with each site to better understand each facility's infrastructure and communication pathways to remove barriers and confirm each site could reach enrollment potential. Labcorp also created online surveys for sites, which resulted in country-specific enrollment plans. The team then evaluated each site's ability to process samples collected from patients, which was critical for study results. In several cases, Labcorp had to engage qualified regional microbiology labs to deliver reliable data for the trial. In other areas, Labcorp contracted regional labs to handle the logistics and process the samples. This helped sites with insufficient lab facilities to culture samples taken from patients and to send isolates to the study's Central Lab for study data.

Throughout the study, Labcorp implemented tailored mitigation strategies for each site by sending out newsletters, connecting with study coordinators and performing motivational visits to understand how to best support each site and their needs for this challenging study.

Meeting enrollment goals and delivering well-organized, high-quality data

As data were generated, Labcorp ran a medical monitoring plan to review the results, check on data sets, perform lab reconciliations, periodically clean data and track screen failure rates and deviations. This proactive strategy allowed the team to take remedial actions in near real-time with specific sites to maintain ongoing, timely enrollment.

As a result of these cross-organizational efforts throughout the trial, enrollment completed on schedule for 351 patients across 14 countries. The sponsor received high-quality data within their original timelines and was ready to proceed to Phase III as planned.

In this challenging antibiotic study, the Labcorp team served as more than a partner to help the sponsor target the right countries and select the right sites, ensuring on-time enrollment. The thorough feasibility process, review of lab data and consultations with medical monitors also helped keep study startup on track. Finally, the selection of qualified regional labs and regular data cleaning and review allowed the team to generate accurate results that supported the analyses of safety, tolerability and efficacy for this novel treatment that could help address an urgent unmet need for patients around the world.

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