CASE STUDY

Addressing barriers to recruitment in a global cUTI drug study

Options to treat complicated urinary tract infections (cUTIs) are increasingly limited because of antibiotic-resistant organisms, stressing the need to explore novel treatments. To serve as a more than a partner to drug development sponsors in this area, Labcorp Drug Development draws from a deep well of scientific expertise to advance these unique investigational products. This case study describes the challenges faced and strategies applied to meet and exceed the target dates for a global cUTI drug.

Addressing high screen failure rates

A large pharmaceutical company chose Labcorp Drug Development to support its ongoing Phase II study evaluating patients with cUTI. Labcorp offered the sponsor extensive experience in efficiently running antibacterial trials and started by collaboratively reviewing historical epidemiological information to select 67 sites across 19 countries.

After recruiting 302 patients, Labcorp worked with the sponsor to develop a timeline for First Patient In, Last Patient In and Last Patient Out, but the study's start was pushed back due to delays in finalizing the protocol.

An even greater impact on the study's timeline emerged when highly restrictive eligibility criteria and other factors affected the enrollment rate. The likelihood of high screen failure rates coupled with an observed high, early microbiologic failure rate led to an observed decrease in site motivation, hampering investigators' recruitment efforts for the study.

Implementing innovative strategies to increase site motivation

The team quickly employed a strategy for continual tracking of real-time microbiology results to identify both types of microbiologic failure and decreased enrollment rates. With statistical analysis, they identified a key difference in late-failure study patients: those patients had received additional, pre-enrollment antibiotic therapy. This finding suggested that the investigators were selecting patients at high risk of recurrence.

Key Takeaways

- Gathered critical, real-time evidence to amend the protocol's restrictive eligibility criteria and correct the course
- Developed a targeted strategy to increase site motivation and improve percentage of evaluable patients
- Reached Last Patient In five months ahead of the sponsor's schedule

Recognizing these issues that were contributing to slow enrollment and site demotivation, Labcorp proactively worked with the sponsor to develop a site management strategy. First, to address the challenging eligibility criteria, Labcorp asked the sites to complete pre-screen logs and collect data on the limitations of the enrollment criteria. With this feedback, the sponsor had tangible evidence that supported dropping the nosocomial requirement and immediately amending the protocol.

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Next, the team worked to maximize communication pathways with the sites. Labcorp not only developed memos and newsletters to keep sites informed at regular intervals but also solicited sites to complete electronic surveys to identify their most urgent enrollment challenges.

Using this direct feedback gathered from the sites, Labcorp developed targeted motivation tools to improve the study's visibility and help investigators recognize it as a top priority. Following this plan, clinical research associates were empowered to perform routine site calls and schedule regular visits, working closely with the sites to address current barriers and provide constructive advice.

The final approach to boost recruitment involved adding new sites in the highest-enrolling countries. Leveraging Xcellerate® Trial Design, which evaluates and identifies the highest-performing investigators by indication and forecasts enrollment rates, the team selected the most optimal sites to add to the European region.

Completing enrollment five months early

With the combined approach of adding new sites, revising eligibility criteria and strengthening the communication pathways, the sites were enabled to rapidly enroll patients and investigators felt motivated to support the study. While enrollment had lagged with the original protocol, requiring 18 months to enroll 113 patients, the amended protocol allowed for faster enrollment of the remaining 189 patients in only 11 months—trimming the sponsor's timeline by nearly five months.

Labcorp also helped the sites deliver 76% microbiologically evaluable patients by implementing an analytical strategy with real-time data, surpassing the sponsor's goal of 65%. As a result of this partnership, the sponsor felt extremely satisfied with the timelines and was impressed by the quality of data as Labcorp exceeded expectations for this challenging global study. This partnership gave the sponsor the data necessary to progress the development of their drug, which could ultimately make a difference for patient care.

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