cUTI Case Study

BARRIERS TO RECRUITMENT IN A GLOBAL cUTI DRUG STUDY

A large pharmaceutical company outsourced its ongoing Phase II study evaluating patients with complicated urinary tract infection. Covance was selected as the sponsor's partner based on its extensive experience in efficiently running antibacterial trials. This case study describes the challenges faced and strategies applied to meet or exceed the target dates for studying this new drug and support the advancement of the investigational product.

The Challenge

Strains of bacteria that can cause urinary tract infections have developed greater resistance to common antibiotics. Options to treat complicated urinary tract infections (cUTIs) are increasingly limited because of these antibiotic-resistant organisms, stressing the need to explore novel treatments.

To address this global health concern, Covance and the sponsor collaboratively reviewed historical epidemiological information to select 67 sites across 19 countries and recruited 302 patients. They developed a timeline for First Patient In (FPI), Last Patient In (LPI) and Last Patient Out (LPO), 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.

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 (LPI) 5 months ahead of the sponsor's schedule

The Actions: Implementing innovative strategies to increase site motivation

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

Recognizing these issues that were contributing to slow enrollment and site demotivation, Covance proactively worked with the sponsor to develop a site management strategy. First, to address the challenging eligibility criteria, Covance 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. Covance 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, Covance developed targeted motivation tools to improve the study's visibility and ensure it was recognized as a top priority for investigators. Following this plan, clinical research associates (CRAs) 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.

The Results: Completing enrollment 5 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.

Covance 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 Covance exceeded expectations for this challenging global study. This partnership ultimately gave the sponsor the data necessary to progress the development of their drug.

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