Phase III cUTI Antibiotic Study

Overcoming Global Challenges and Meeting Enrollment

Sponsor Challenges

Where did anyone see an easy Phase 3 trial lately: timelines slip, vendors get acquired, standards of care change, interest dwindles, competition doesn't stand still...the list goes on and on. These studies are meticulous and require a great amount of time and attention. With a study of this magnitude, ensuring the quality of data globally was also critical.

At a glance

Antibiotic development is notoriously underfunded, so running a pivotal phase 3 study can be a challenge. From the beginning, PSI supported the sponsor by leveraging our global site relationships and experience with pivotal antibiotic trials for the most pragmatic site selection. This helped us enroll the trial at a rate 23% higher than industry metrics in the same indication, with Last Patient In (LPI) occurring during the peak of the first COVID-19 wave. It wouldn't have been possible without our investment in building close site relationships – because our CRAs act as site ambassadors, sites want to work with PSI and prioritize our studies, even in the midst of a pandemic.

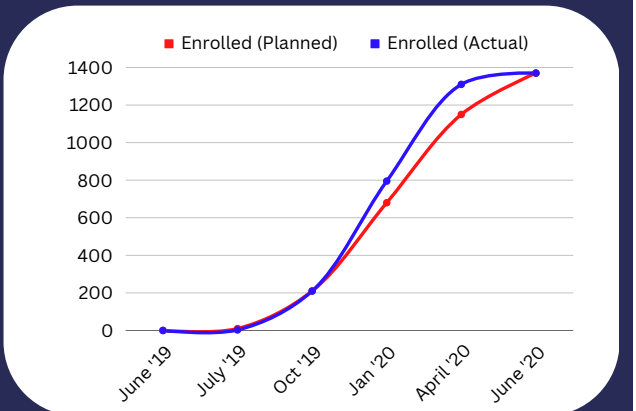
Key Metrics

1450
Screened Patients

1370
Randomized Patients

15
Countries

100
Trial Sites



PSI Strategy

1 Antibiotic Experience

PSI's strategy for delivering these studies has been tried and tested, ensuring our sponsors the most effective way to deliver antibiotics to market. We also have experience working with BARDA, so we were able to manage the complexities of working with them on this study.

2 The Right Team

PSI invests time and resources to build close site relationships; we empower our CRAs to go further than is typical across the industry. This means sites want to work with PSI, they prioritize our studies, and we understand their preferred methods of working and individual quirks.

3 Commitment to Quality

The team understood that delivering the data on time was crucial for the study's success. PSI used a network of regional microbiology labs to ensure the quality of data globally. Despite COVID-19 lockdowns and limited access to sites and patients, our CRAs were able to work closely with site staff to understand each site's individual needs and processes and ensure that all necessary data was collected and cleaned in time to meet key trial milestones such as the database lock.

Results

- Enrollment rate 23% higher than industry metrics in the same indication
- More than 95% of sites enrolling patients
- Enrollment of 1,450 patients delivered in 11 months
- Screen failure rate of only 5%

Contact us