Premier Insight 277

Optimizing Enrollment for a Phase 3 Clinical Trial During a Global Pandemic

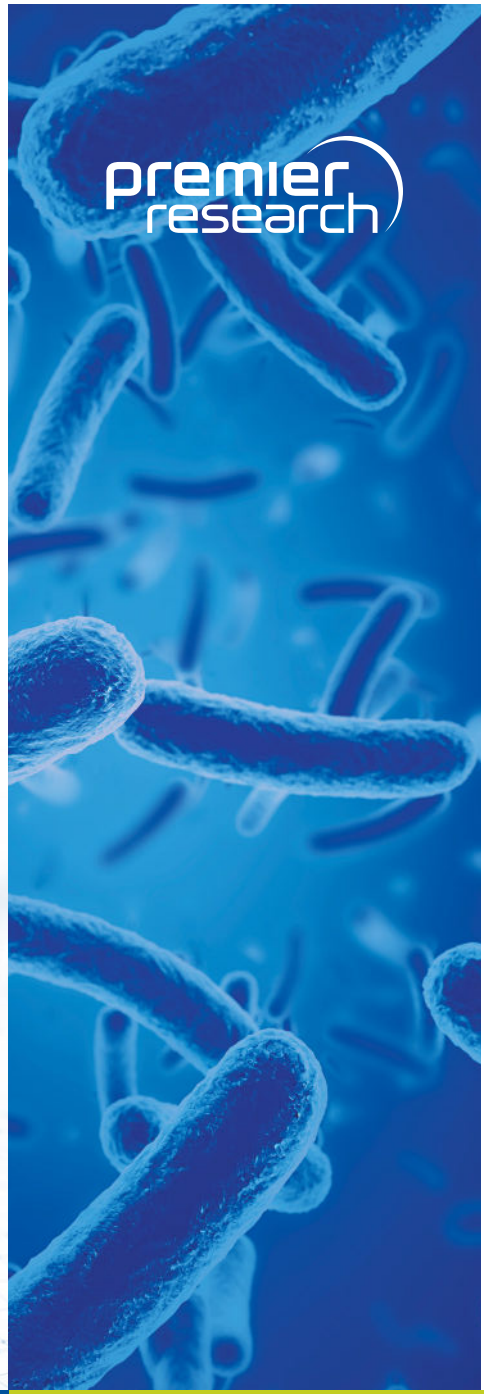
Background

A biopharmaceutical company focused on delivering innovative products for women's health chose us to manage their Phase 3 clinical trial evaluating an investigational, thermosetting, bioadhesive hydrogel for bacterial vaginosis (BV). We leveraged our expertise in study design and execution along with our extensive network of OB/GYNs to deliver a successful clinical study ahead of schedule.

This multicenter, randomized, double-blind, placebo-controlled study of treatment for women with bacterial vaginosis was set to begin just as COVID-19 was shutting down much of the United States. Clinical site engagement and patient enrollment were threatened by fear of the pandemic, local stay-at-home orders, and altered clinic procedures. The sponsor did not, however, want to delay the study start as bacterial vaginosis is a significant health issue facing women.

Study Sites	Patients Enrolled	Months Duration
32	307	6

Premier Research Phase 3 study of an investigational thermosetting bioadhesive hydrogel for bacterial vaginosis



WOMEN'S HEALTH CLINICAL RESEARCH

Challenges

1. **Study start-up activities** typically require travel to perform onsite visits to ensure that site facilities and staff are thoroughly assessed ahead of site selection or moving forward with study-related activities. Social distancing limitations put in place to ease the threat of viral transmission proved to be a contending challenge facing most clinical trials during the COVID-19 pandemic.

Mitigations

- Adopted virtual methods for site selection and initiation visits, secure electronic file management for site monitoring, and an online platform to access training recordings and documents
- Defined strict criteria for site selection including prior relationship with the sponsor, previous participation in one or more BV studies, and experience with 10+ patients per month with BV symptoms

2. **Site management and data collection activities** are typically carried out in-person to establish expectations and standards for conduct and communication during the course of a clinical trial. This trial presented with rapid data collection needs that were unexpected given the anticipated enrollment challenges in the COVID-19 environment. Some of the standard site management activities could not be carried out in-person due to social distancing restrictions and varying levels of comfort related to traveling and in-person interactions.

Mitigations

- Conducted a virtual investigators meeting to emphasize key guidelines including protocol details, therapeutic specifics for BV, new FDA guidance, and review of all virtual monitoring resources to accommodate evolving restrictions and conditions during the COVID-19 pandemic
- Communicated regularly and frequently with sites and the sponsor to proactively identify and address issues in real time
- Collected and monitored data rapidly through in-person and remote methods to accommodate the speedy pace of enrollment without sacrificing data quality

3**. Participant engagement** is a common challenge for many clinical trials, even under normal circumstances. In the COVID-19 environment we had to navigate "new norms" relating to the screening eligibility process, communication flow, and study related activities.

Mitigations

- Anticipating in-person patient engagement challenges, utilized local advertising strategies to reach and connect with the target patient population
- Supported the use of a patient recruitment vendor, allowing participants to prescreen for eligibility using a virtual screener
- Communicated with the sites and their participants to proactively mitigate any confusion or discomfort pertaining to COVID-19 restrictions. In turn, we, along with the sponsor, provided the sites extra training and support
- Focused our selection of well-equipped, well-practiced sites with a history of successfully engaging and enrolling BV patients

Takeaway

The successful delivery of this clinical trial ahead of schedule was the result of several purposeful and proactive measures implemented with the sponsor and the sites. Enrollment was nearly twice as fast as initially anticipated, despite the COVID-19 pandemic. The team's collective ability to quickly pivot and adapt to new restrictions and demands, including implementing virtual and decentralized trial management options, ensured that delays were avoided and accommodations were identified.

Study Description

Phase 3 study of an investigational thermosetting bioadhesive hydrogel for bacterial vaginosis

Therapeutic Area

Women's Health

Geographic Scope

U.S.

Number of Study Sites

32

Number of Patients Enrolled

307

Duration

6 months

Outcome

One hundred percent of patients enrolled two times faster than past bacterial vaginosis studies with a screen failure rate 2.5 times higher than past studies.

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