Premier Insight 282

Leveraging the Power of Communication: Supporting Enrollment of a Phase 2 Cervical Cancer Study During a Pandemic

Background

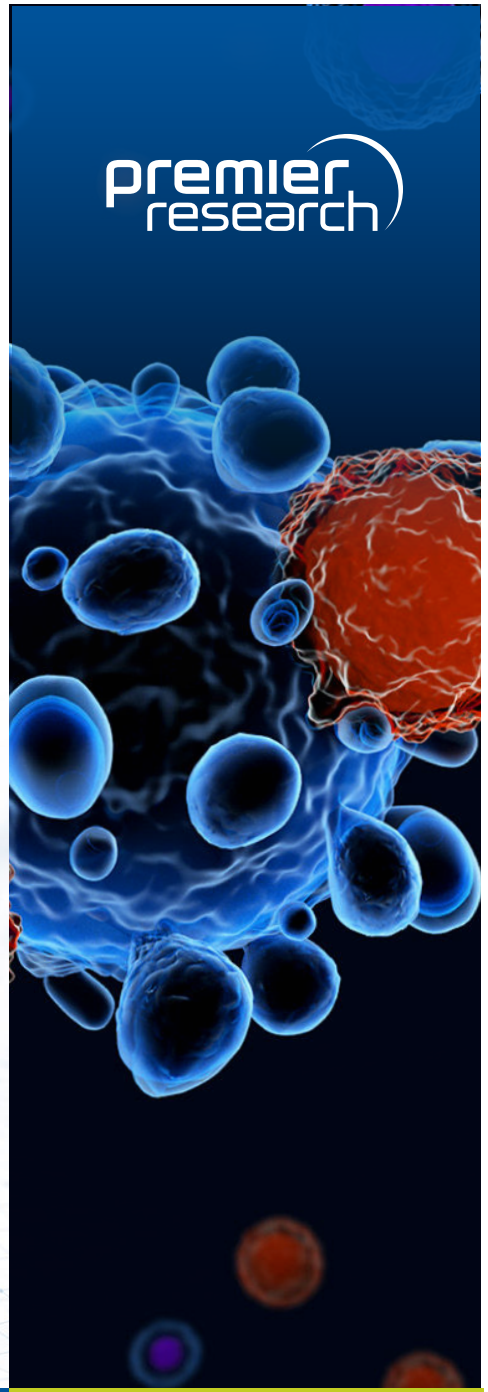
Cervical cancer is the fourth most common cancer in women. Despite being highly preventable, over 600,000 women were diagnosed and more than 340,000 died from the disease worldwide in 2020. The majority of cervical cancers are caused by infection with human papillomavirus (HPV) and the implementation of HPV vaccines has been shown to reduce the risk of developing invasive cervical cancer. For women with recurrent or metastatic cervical cancer, however, there remains a high unmet clinical need due to lack of standard of care after progression on first-line treatment.

Objective

The developer of an investigative medicinal product (IMP) for advanced, recurrent, non-resectable cervical cancer engaged Premier Research to assist with screening and enrollment in a Phase 2 study in Europe.

Planned vs. Actual Study Statistics

	Planned / Expected	Actual
Date of First Patient In	June 1, 2020	July 1, 2020
Date of Last Patient In	December 31, 2021	February 10, 2022
Number of Sites	23	19
Number of Patients Screened	58	116
Number of Patients Enrolled	50	52
Screen Failure Rate	14%	55%
Enrollment Rate	26%	17%



ONCOLOGY

Meeting the Challenges

As this study was initiated just prior to the COVID-19 public health emergency, regulatory review and study start-up activities were adversely impacted:

- Regulatory review was held up due to diversion of resources to pandemic management
- Multiple sites experienced staffing shortages that resulted in delays in essential document provision, contract negotiation, and other activities

Consequently, site activation proceeded more slowly than expected. Enrollment was also hampered by obstacles related to the patient population and study design:

- Screen failure rate was significantly higher than projected, in part due to discrepancies between local and central lab results and the fragility of the target patient population
- The target patient population included end-stage patients who were close to progression and often quite ill and weak
- The protocol involved an extensive visit schedule and required numerous sample draws

Our Strategy

Premier focused on:

- Putting together the right team to drive the study forward, despite pandemic- and study-related hurdles
- Optimizing investigator and site engagement to increase the screening rate and boost enrollment

Solutions

- Leveraged Premier's global network of sites to identify those with a high likelihood of success in this rare indication
- Initiated and maintained close contact with both the regulatory authorities and the sites, enabling achievement of first patient in with only a minor delay and higher than expected screening and enrollment
- Offered additional support to sites to offset resource shortages
- Specified an individual – often the principal investigator (PI) – responsible for driving enrollment at the site level and established routine communications. If that person became unavailable due to COVID-related responsibilities, a new individual was identified as a replacement
- Provided sites with regular reminders to review patients for study eligibility, keeping the study top of mind and ultimately screening double the number of patients planned and enrolling two patients more than the target
- Identified specific site team members who were responsible for other essential activities, creating personal connections and increasing both engagement and accountability
- Adjusted timelines to account for unavoidable pandemic-related factors, minimizing the impact on enrollment delays

Takeaway

When unexpected challenges arise, establishing and maintaining close communication among the sponsor, PIs, and sites is critical for meeting enrollment targets and minimizing study delays. Flexibility and persistence are also essential for sustaining engagement. Due to Premier's ability to pivot and perform under pressure in this study, the sponsor awarded Premier another Phase 2 study with this same IMP in a different oncology indication.

Study Description

Phase 2 study of advanced, recurrent, non-resectable cervical cancer

Therapeutic Area

Oncology

Geographic Scope

Seven countries in Europe (Germany, Poland, Bulgaria, Belgium, France, Czech Republic, and Norway)

Number of Study Sites

19

Number of Patients Enrolled

52

Outcome

Enrollment exceeded target despite slower than expected study start-up due to COVID-19 constraints, fewer sites, and higher than anticipated screen failure rate.

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