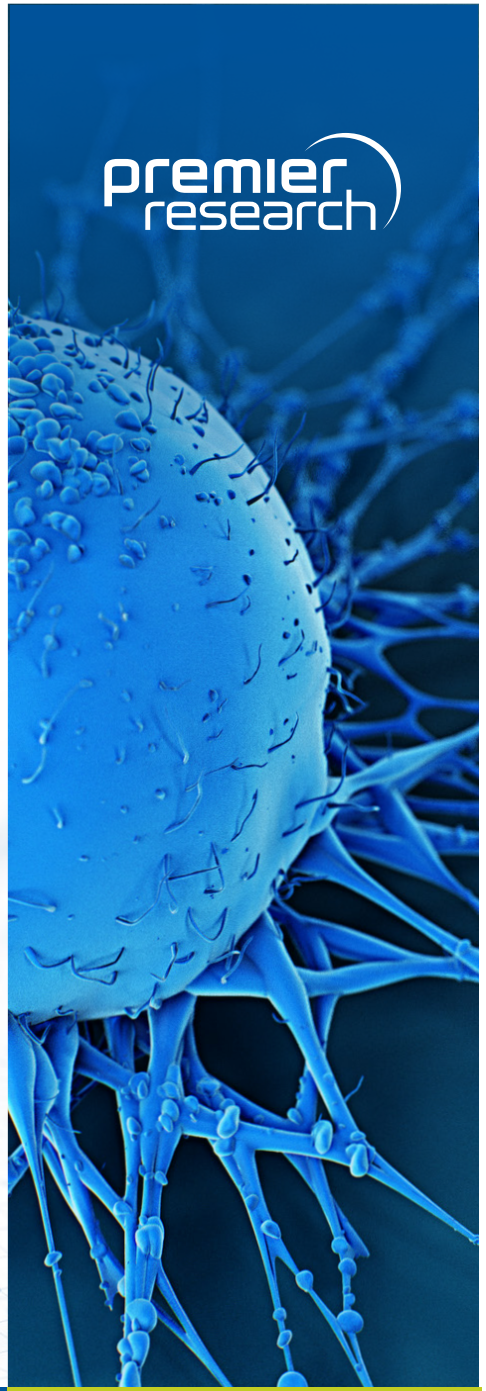
Premier Insight 281

Overcoming Enrollment Challenges in a Phase 2 Prostate Cancer Clinical Trial

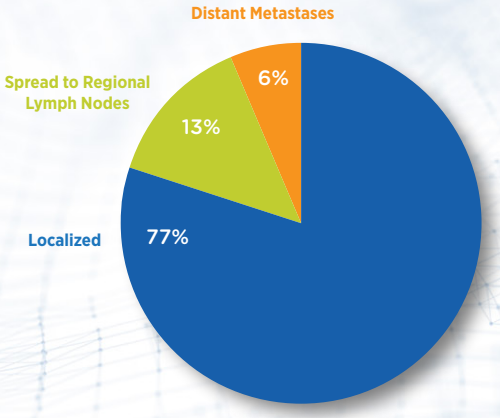


Background

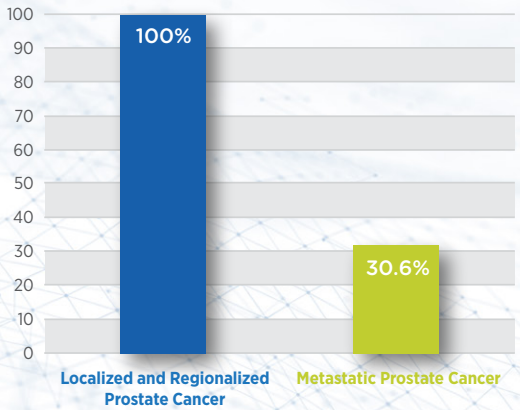
Prostate cancer (PC) is among the most commonly diagnosed cancers overall, and the most frequently diagnosed cancer in men. The 2018 global estimate of new PC cases exceeded 1.2 million with more than 350,000 deaths worldwide. Over the last decade, new treatments combined with better use of existing therapies in early-stage disease have transformed the PC therapeutic landscape, and new imaging and sequencing technologies have improved screening and detection rates. Nevertheless, many patients present with intermediate or high-risk localized, locally advanced, or metastatic PC and, despite treatment, succumb to the disease. Even though no curative treatment exists for metastatic PC (mPC), the past several years have seen a steady increase in active trials for metastatic, castration-resistant PC (mCRPC) therapies, particularly in the U.S. This has led to increased competition for patients and slower recruitment in mCRPC treatment trials.

Objective

A U.S.-based developer of an investigative therapy for mCRPC engaged Premier Research to increase enrollment in a Phase 2 mCRPC study involving 100 patients at six sites in the United States.



Prostate Cancer Cases at Diagnosis



Five-year Relative Survival Rate

ONCOLOGY

Meeting the Challenges

1. Before finalizing the protocol, a new arm was added in which participants would receive a recently approved PARP inhibitor– the new standard of care – which was a direct competitor to the sponsor's product. This change was made without consulting Premier, study investigators, or key opinion leaders (KOLs); nor was a formal competitive analysis conducted during feasibility assessment. As a result patients had little incentive to enroll in the new arm now that this product was available outside a clinical trial.
2. The final protocol contained amended eligibility criteria from the initial limiting the patient population so narrowly that it excluded many patients who might have been a good fit for the study.
3. In the combination-therapy arm, the medication administered concomitantly appeared to cause hypokalemia, resulting in a higher than expected patient drop-out rate.

Our Strategy

Premier recommended:

- Expanding the study to Europe, where the mCRPC clinical trial landscape was less competitive
- Creating a new feasibility questionnaire with KOL input on proposed protocol amendments to make the study more inclusive and boost enrollment

Solutions

- Instituted a series of calls to allow Premier's clinical research associates to engage more directly with study personnel
- Conducted bi-weekly calls with the study's principal investigators (PIs) regarding issues affecting enrollment and overall site performance
- Presented PIs with efficacy data on the sponsor's drug, making them more enthusiastic about enrolling patients into this trial instead of other active studies at their sites
- Added a urologist as a sub-investigator at each site based on the recognition that many patients, particularly in rural areas, preferred to receive care from their urologist rather than travel to a major cancer center – empowering the urologists to refer patients to the trial
- Fielded PI surveys to gather intelligence on enrollment challenges
- Developed recruitment, screening, and enrollment plans in partnership with each site
- Closed inactive sites and activated additional site in Europe

Takeaway

To ensure smooth enrollment, engage KOLs at the protocol design stage and create site-specific planning pre-launch. Looking more closely at mCRPC, this study demonstrated the importance of assessing the indication-specific clinical trial landscape. Premier put this Phase 2 mCRPC trial back on track to meet study milestones with increased site engagement, expansion of study sites to different regions, and tailored protocol amendments designed to facilitate enrollment.

Study Description

Phase 2 mCRPC study involving 110 patients at six sites in the U.S. and Europe

Therapeutic Area

Oncology

Geographic Scope

United States and Europe

Number of Study Sites

Six

Number of Patients Enrolled

Study is still enrolling

Outcome

Enrollment in the Phase 2 mCRPC trial was put on track to meet study milestones due to increased site engagement, expansion of study sites to different regions, and tailored protocol amendments designed to facilitate enrollment.

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