TMC
Tailored Solutions.
Proven Results.

CASE STUDY

Global Phase 3 Clinical Trial in Metastatic Prostate Cancer:

Efficient patient enrolment and successful project delivery during the COVID-19 pandemic

Background & Objectives

Prostate cancer remains the second leading cause of male cancer-related mortality, according to the American Cancer Society. Early-stage, localised disease, can be cured, but the prognosis for men with metastatic disease is poor. Although advancements are being made in the treatment of prostate cancer, some needs still largely go unaddressed.

A US-based Biotech company, developing a diverse pipeline of specialty drugs that bring clinically meaningful benefits to patients with serious or debilitating diseases in which treatment options are limited, randomised 108 patients with metastatic Castrate Sensitive Prostate Cancer (mCSPC) and metastatic Castrate Resistant Prostate Cancer (mCRPC), to conduct a pivotal Phase 3 study at 42 sites across the USA, UK and Europe.

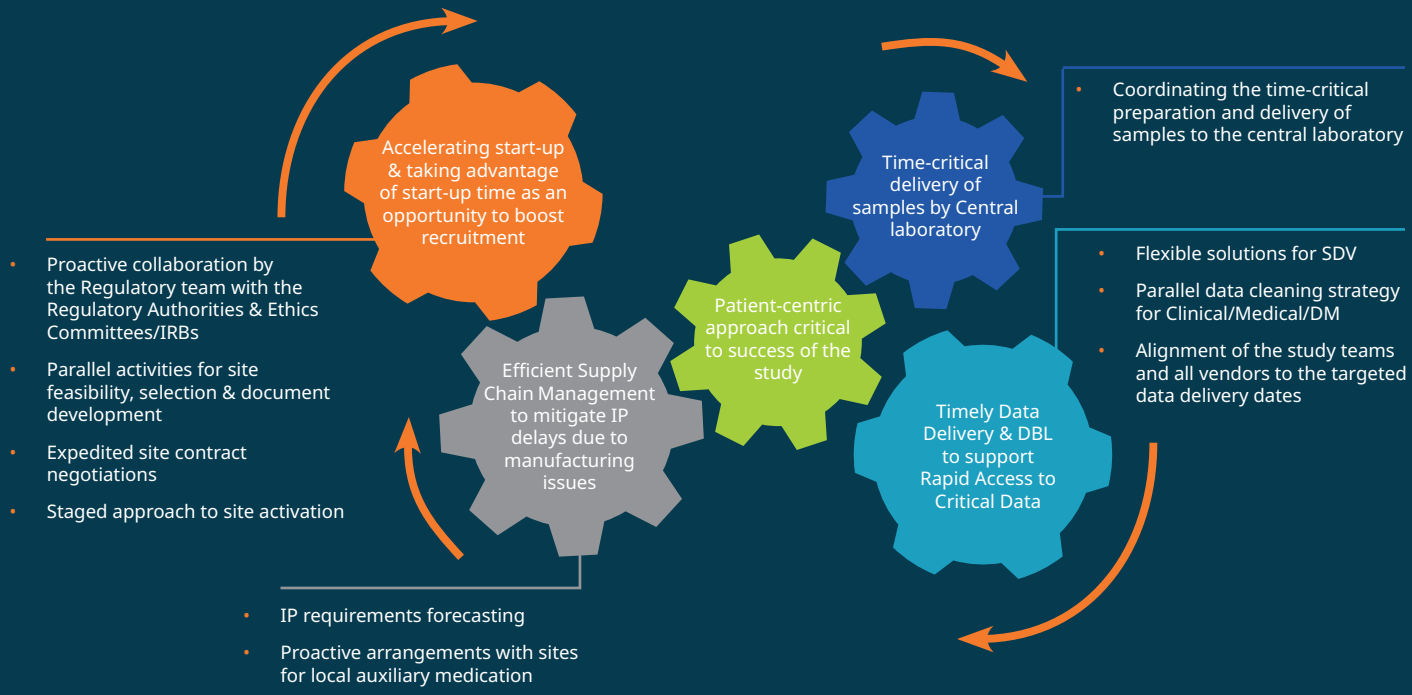
Study design	A pivotal phase 3 study to investigate the efficacy and safety of a novel formulation of the Study Drug in mCSPC and mCRPC
Purpose of study	NDA enabling to show comparable efficacy/safety of novel formulation with standard formulation
Number of patients	108 (n=54 patients per prostate cancer population)
Number of sites	42 sites globally (US, UK, ES, HU, PO, FR)

"I cannot even begin to thank you for all your hard work over the last few weeks driving towards DBL. Every time there seemed to be a light at the end of the tunnel – we added another hurdle! You handled absolutely everything we threw at you brilliantly!"

Head of Clinical Project Management, Biotech Client

Challenges & Solutions

TMC Pharma Services was requested to provide support with patient recruitment and proved that a patient-centric recruitment strategy, with a focus on optimising site engagement and proactively mitigating other project challenges, can overcome potential obstacles and deliver on time, despite the COVID-19 pandemic.



Outcome

- TMC's proactive approach and risk mitigation strategy ensured that patient recruitment to the pivotal study was completed on time and within the required time frame, despite the operational challenges posed by the COVID pandemic.
- All quality metrics for the study were met & successfully audited.
- The asset is now in pre-registration stage.