MEDPACE

CASE STUDY

ACCELERATING STUDY ENROLLMENT FOR NON-MUSCLE INVASIVE BLADDER CANCER (NMIBC)

BACKGROUND

An innovate biotech conducting a Phase III non-muscle invasive bladder cancer clinical research study partnered with Medpace to help support its development efforts. Study objectives were to evaluate the safety and efficacy of a new gene therapy which was administered intravesical to patients who had recurrent bladder cancer within six months after a failed induction and maintenance course of Bacillus Calmette Guerin (BCG) treatments.

Patient enrollment was at a standstill — Medpace's Patient Recruitment and Retention team was called in to help enroll the study and keep it moving forward.

RECRUITMENT CHALLENGES

Because this study was in patients who had recurrent bladder cancer within six months after a failed course of BCG treatments, it was extremely difficult to find and enroll patients. Less than 10% of patients are unresponsive to BCG treatments so the patient population was limited. There were specific timelines for patient enrollment based on diagnosis, previous BCG treatments, and tumor recurrence. This made it challenging to determine when a patient could become eligible to be enrolled and randomized. Site capacity was also an issue as there was a significant time commitment for site staff to pre-screen patients and conduct quality chart reviews.

RESULT:

Medpace's Patient Recruitment and Retention team jump-started recruitment and successfully met study timelines.

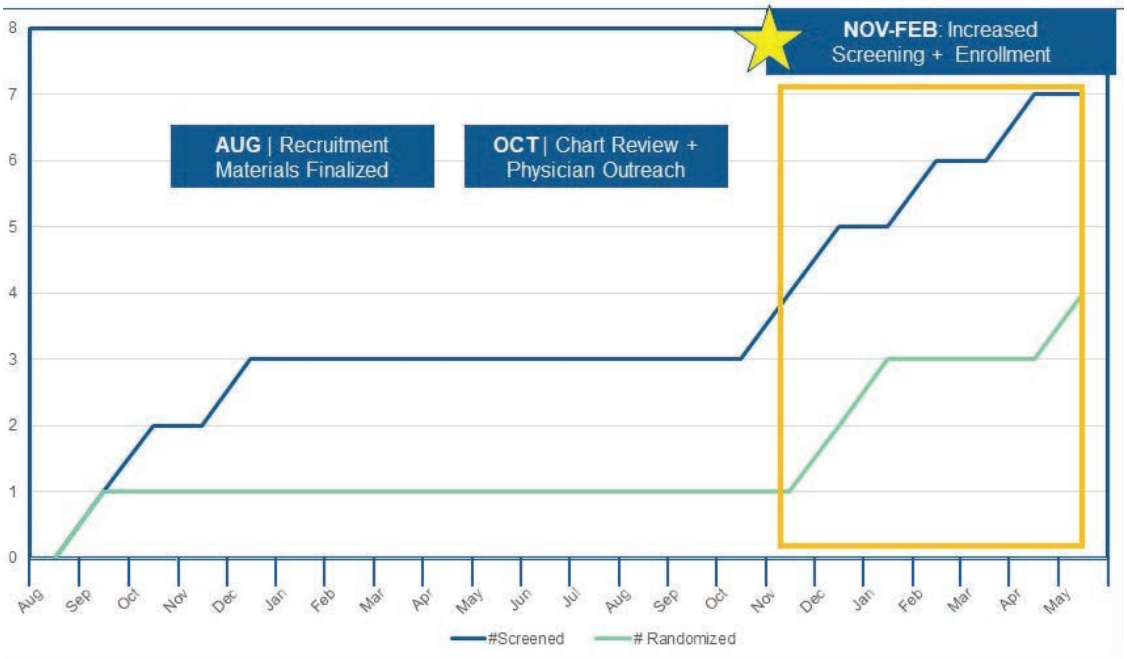
8 POTENTIAL PATIENTS IDENTIFIED BY CHART REVIEW

1 PATIENT RANDOMIZED FROM CHART REVIEW

RANDOMIZATION INCREASED BY **25%**

3-5 ACHIEVED SITE ENROLLMENT GOAL OF PATIENTS

Results obtained from one study site.



SOLUTION

Personalized Chart Review and Support: Many sites had potential protocol-eligible patients, but they often lacked the time and resources needed to identify them while still within the window. The patient recruitment team at Medpace reached out to all of the sites in the study offering our chart review service to find potential patients. The sites who agreed appreciated the extra support and resources. For one particular site in Myrtle Beach, South Carolina, Medpace developed a query within the site's EMR system and pulled a list of 75 bladder cancer patients who had recent BCG treatments. Medpace conducted comprehensive individual chart reviews and completed a pre-screen checklist noting relevant BCG treatments, when the last course of treatment was, and when the patient would fall within the eligibility window. The cumbersome pre-identification process for the sites was lifted and they could jump into screening patients when they became eligible.

Raising Awareness for Physicians and Sites: Patients who are unresponsive to BCG treatments have limited treatment options. As a result, it was critical to raise awareness about the trial among physicians. Medpace's recruitment team conducted physician outreach to seven urology centers to inform and educate the staff of a clinical trial being conducted in their area. The team introduced the study and left materials to over 30 staff so they could refer eligible patients as they came in for visits.

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.

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