MEDPACE

CASE STUDY

WELL-DESIGNED AND EXECUTED PHASE II SAFETY STUDY SET THE STAGE FOR PROGRAM SUCCESS

BACKGROUND

A drug manufacturer conducting a Phase II clinical research safety study for a compound to treat patients with complicated urinary tract infections (cUTIs) or acute pyelonephritis partnered with Medpace to help support its development efforts. Study objectives were to evaluate the safety and efficacy of their compound prior to commencing a Phase III study, which would focus on target pathogens.

The Phase II study was completed ahead of projections — Medpace applied experience, relationships and operational acumen to design and execute the optimal strategy.

CHALLENGES

Limited Drug Availability: Country and site selection were critical to the success of this trial because of the limited availability of drug. Additionally, of the four countries selected, three had their own depots so once the drug went into those countries, it could not come back out. Managing the limited drug availability and ensuring there was enough – but not too much – drug to cover the 7 to 14 days of treatment required constant assessment and management.

Speed was Essential: Data from this Phase II study was required to finalize the core documents for the Sponsor's Phase III study. With only a three month window planned from database lock to a final Phase III protocol, the trial needed accelerated enrollment and site start-up to ensure the program remained on schedule.

Global Communication: The Phase II clinical trial was conducted in Eastern Europe (80 treated patients, 4 countries, 20 sites). To meet and exceed timelines while treating the unique needs of patients with cUTI or acute pyelonephritis required a seamless global communication strategy between the Medpace team located in Europe and the Sponsor team located in the United States.

Patient Recruitment in an Acute Setting: Patient enrollment was challenging because patients could present at the hospital in various departments. It was critical that patient flow was identified at the sites and a process put in place to triage to the appropriate unit where the investigator was located. Additionally, patients needed to be hospitalized for the duration of the treatment – 7-14 days.

RESULT:

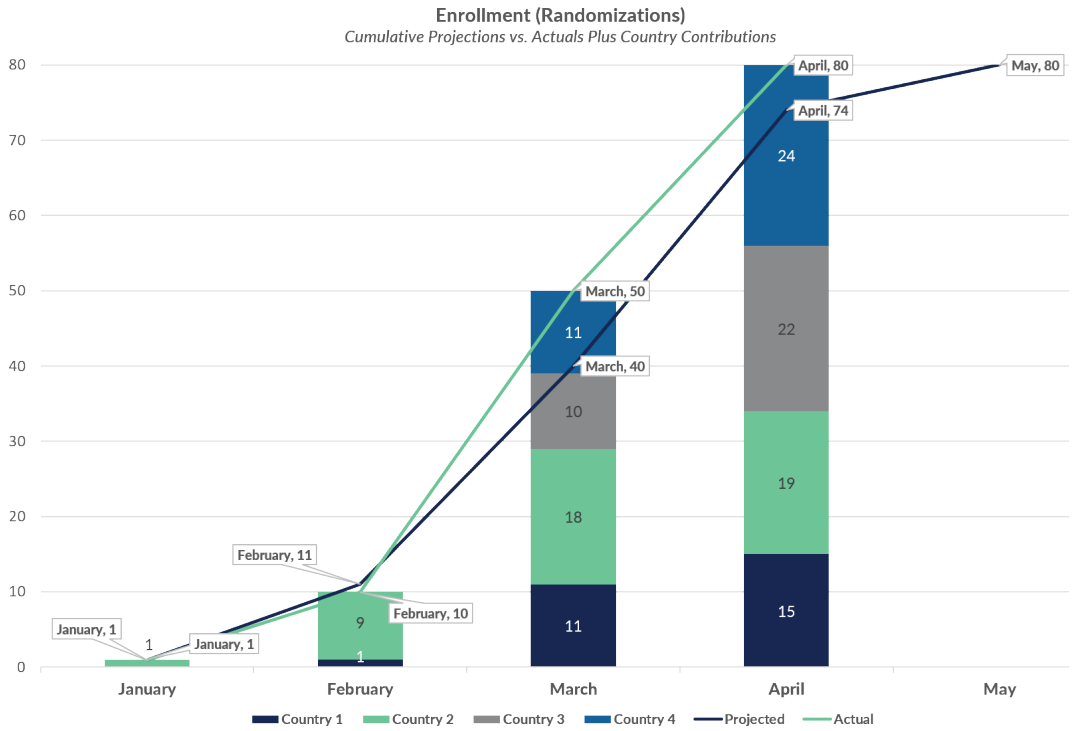
Expedited Site Selection, Start-Up and Enrollment

2.7 MONTHS ENROLLMENT PERIOD
SURPASSING THE PROJECTED GOAL OF 4 MONTHS

50% HIGHER PATIENT ENROLLMENTS
PER SITE/PER MONTH OVER PROJECTIONS

6.6 MONTHS STARTUP
FROM THE FINAL CORE DOCUMENT TO LAST SITE INITIATION VISIT

All sites contributed to study enrollment.



SOLUTION

Prior Experience Drives Sound Strategy: Medpace had direct and recent experience conducting similar studies. Applying lessons-learned, we were able to rapidly identify the appropriate sites that had a history of strong performance in this setting. The sites selected were those with efficient startup processes, familiar with a blinded/unblinded protocol, and were experienced in working closely with the microbiology labs and other hospital departments to ensure each potential patient was not missed.

Site and Country Selection: Aligning the target population with high-performing sites was critical to meeting enrollment timelines. Medpace has the global footprint and a strong history of working on infectious disease trials, including cUTI trials. With the resources and relationships, coupled with the data from the prior trials, we were able to confidently select the countries and sites that could meet enrollment milestones.

Up-front Planning and Ongoing Oversight for Drug Availability: Streamlined communication and planning was critical in a trial with this timeline and complexity. With existing site relationships in place, there were efficiencies in determining drug availability. Using prior metrics, we were able to accurately project enrollment per country and then develop country-level supply plans based on those enrollment expectations. We were upfront with the sites about limited drug availability which motivated them to enroll quickly. Our unblinded team kept a keen eye on the supply thresholds and judiciously triggered resupply as needed and closed off countries to recruitment if there was not enough drug available to maintain the blind with further enrollment.

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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