Case Study:

ADVANCING A FIRST-IN-CLASS VACCINE IN KIDNEY TRANSPLANTATION

BACKGROUND

Kidney transplantation is the gold-standard therapy for End-Stage Kidney Disease (ESKD), yet post-transplant complications and graft dysfunction remain major drivers of long-term morbidity. New treatments, such as vaccines that protect transplant recipients from infection and reactivation of dormant viruses, are a key focus in transplant medicine. However, conducting clinical trials in this population is uniquely challenging.

The following case study outlines Medpace's successful approach to a global clinical trial evaluating an investigational intramuscular vaccine administered pre-transplant.

STUDY OVERVIEW

RESULTS

Successful Enrollment in a Rare Subset: Despite a narrow pre-transplant window and donor-specific eligibility, the study successfully enrolled 80 patients across 42 sites in 9 countries.

High Operational Compliance: Sites consistently met protocol requirements for pre-transplant IP administration, reactogenicity assessment, PBMC sampling, and safety follow-up, which were critical components for data integrity.

Enhanced Global Site Engagement: A coordinated global model, centralized tracking, and dedicated recruitment touchpoints ensured sustained screening activity across all regions.

STUDY CHALLENGES

Rare Patient Population: Study-specific mismatch criteria and donor-specific eligibility criteria limited the pool of potential participants and increased pre-screening burden. Eligible participants represented a small subset of the transplant waiting list, and the unpredictable nature of donor availability required rapid coordination and decision-making.

Pre-Transplant Enrollment Constraints: IP had to be administered prior to transplant, creating a narrow operational window and requiring readiness from both the sites and patients.

Post-Transplant Study Visit Compliance: Following transplantation, patients naturally prioritized routine follow-up visits rather than the additional research appointments. Aligning study assessments with institution standards for post-transplant follow-up visits was critical to maintaining compliance.

MEDPACE SOLUTIONS

Strategic Site Selection: Medpace partnered with sites that maintained large, well-organized transplant waiting lists and donor exchange programs to maximize access to eligible patients.

Centralized and Proactive Patient Identification: Medpace established an early and highly coordinated process that included continuous ad-hoc review of pre-screened candidates, frequent review calls with each site, and centralized tracking of all pre-screening activity through Medpace's integrated, intuitive technology platform. Educational materials were developed to create and foster study awareness across institutions and site referral networks.

Comprehensive Training & Procedure Preparation: Sites received intensive, practical training, covering reactogenicity and PBMC sample processing.

Patient-Focused Education and Engagement: Developed in collaboration with in-house Advanced Clinical Practitioners and investigators, study materials helped educate patients on expectations and the pre-transplant timeline and post-transplant follow-up. Site staff were also provided tools to help communicate the value and importance of additional post-transplant study visits.

Real-Time Safety Oversight: Safety signal notifications to the medical monitoring team enabled rapid evaluation and standardized communication to global sites.

Employed Elements of Decentralized Clinical Trial Management: To reduce patient burden and improve compliance, the study incorporated remote telephone visits and local lab draws through primary care physicians or mobile 'flying' nurses.