CONNECTING THE DOTS FOR GLOBAL VACCINE CLINICAL RESEARCH

MEDICAL LEADERSHIP

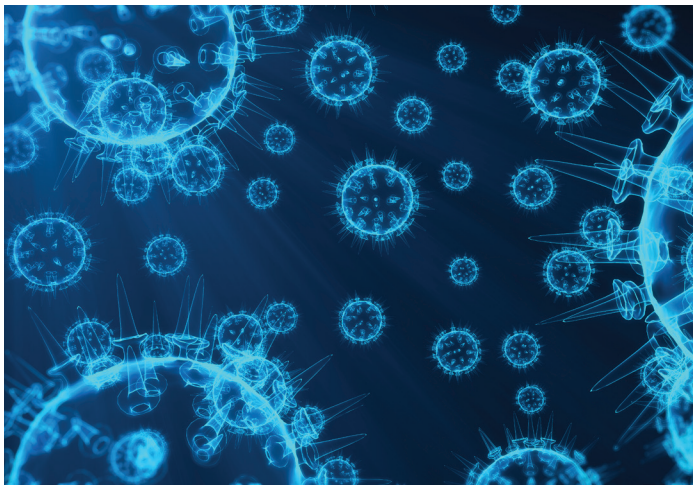
A unique scientifically-driven approach to clinical development delivers the advantage of early and ongoing insight and guidance from Infectious Diseases physicians with expertise in vaccine development in adults and children. Medpace experts provide strategic direction for study design and planning, train operational staff, work closely with investigators, provide medical monitoring, and meet with regulatory agencies. This hands-on approach provides significant advantages that can shorten drug development timelines and reduce development risk.

REGULATORY

Global Regulatory Affairs, Medical Writing and Regulatory Submissions experts bring scientific knowledge and strategic guidance to the vaccine development process. Led by former government officials and subject matter experts, Medpace provides comprehensive international support to Sponsors at all stages of the vaccine development process.

GLOBAL FOOTPRINT

Medpace has the global reach to conduct vaccine studies around the world. We deliver custom solutions specific to your needs on six continents. Projects are facilitated through regional offices located throughout Europe, North America, Asia, Australia, South Africa, and the Americas, with staff and offices continually added throughout the world. The Medpace team has a deep understanding of local language, culture, and processes, creating better relationships with investigators and improved trial execution. Through our regional and local relationships, we have greater access to the country patient populations for faster enrollment timelines and lower costs.



DATA QUALITY AND INTEGRATION

The Medpace global footprint is interconnected through ClinTrak® — an innovative suite of clinical study management technologies — which gives sponsors and study managers near real-time access to critical study and laboratory data that supports project decisions on a global level. Seamless data integration across all study phases, EDC, and support for risk-based monitoring combine to provide a powerful tool that improves timelines, quality and efficiency.

SITE AND KOL RELATIONSHIPS

Medpace has established long-term relationships with successful, experienced sites around the globe. Our physicians and clinical operations teams personally build relationships with principal investigators and opinion leaders worldwide. We can select the best sites for your specific program, providing an advantage in meeting your recruitment timelines with high quality data. Medpace has received multiple awards from investigator sites recognizing Medpace as a leading global CRO.

SPECIALIZED LAB SUPPORT

Medpace Global Labs provides logistical and laboratory testing support for vaccines and biologics trials over the clinical program continuum. Services include pre- and post-analytical support, specimen collection, and logistics and management support for regional, national and global sites. Together with specialized laboratory partnerships, Medpace offers capabilities to support vaccine development efforts including measurement of antibody titers, seroconversion rates, cytokine production, cell-mediate responses and genetic markers, represented by immunoassays, genomics, immunogenicity, and functional cellular assays.

PHASE I UNIT

A state-of-the-art Phase I unit is located on Medpace's one-of-a-kind Clinical Research Campus that facilitates the company's centralized, full-service approach to clinical development. The campus supports a collaborative culture where top early phase, medical, regulatory, clinical operations, and laboratory experts can work cohesively to streamline and accelerate research. The Phase I unit has a robust volunteer database and the infrastructure to recruit for vaccine trials. The facility is attractive to patient volunteers and is supported by a highly experienced research staff that works efficiently throughout enrollment and follow-up.

REAL WORLD EVIDENCE — LATE PHASE

Vaccines often require real world late phase support following approval. Medpace has an experienced team of late phase, epidemiology, and regulatory experts to guide post-approval strategies and study design throughout your program to satisfy the evolving requirements of regulators, payers, providers and patients.

FUNDING STRATEGIES

Medpace has experience working with government grant funded programs, including BARDA, NIH, and the Wellcome Trust. We can assist in meeting the rigorous reporting requirements and associated timelines with government funding. Additionally, Medpace is approved in the Central Contracting Registration (CCR), the primary vendor database for the US federal government.

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.