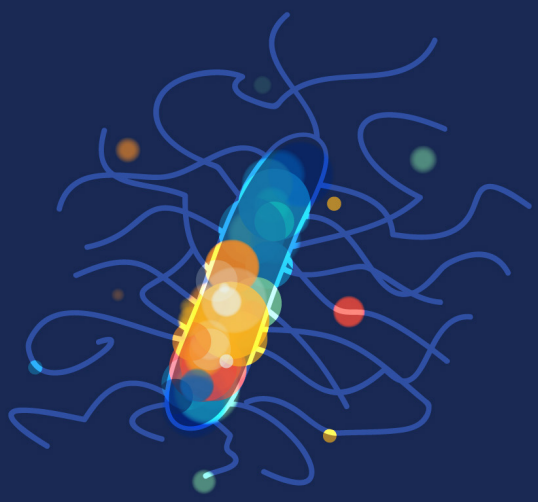
MEDPACE

VACCINE CLINICAL DEVELOPMENT

Vaccine development is essential in the prevention of high-risk diseases, and there are nuances Sponsors and CROs must understand, including the potential for fast-paced enrollment, the epidemiology of emerging and resistant pathogens, and evolving technological advancements in vaccine development. Our collaborative team of experts understand the complexities of vaccine trials from the perspective of the Sponsor, the clinical investigator, the scientific leader, and the reviewer at the regulatory agencies. We bring these perspectives to each vaccine clinical trial that we conduct.

Over 90% of Medpace clients are small to mid-sized biotech companies. As a CRO dedicated to this market, we possess a deep understanding of the inherent challenges that biotechs face. Medpace's vaccine team provides expertise and a consistent track record of success across a variety of therapeutic areas. This ensures a flexible and nimble team required for the unique needs of vaccine trials.

To streamline clinical development and maximize the probability of success, Medpace provides medical and operational experts, therapeutic experience, disciplined processes, site relationships, and technologies to execute vaccine studies.



EXPERTS

- A collaborative cross-functional team of medical, regulatory and clinical experts with extensive experience designing and conducting vaccine clinical trials
- Led by noted experts in infectious diseases and vaccines, Medpace medical doctors are deeply embedded in your trials from protocol design through submission
- Advanced Nurse Practitioners provide an additional layer of expertise including patient and site perspectives

EXPERIENCE

- Global Phase I-IV trial experience
- Broad experience across a wide range of vaccine types and populations
- Therapeutically-aligned functional teams with a deep understanding of the complexities of vaccine trials

EXECUTION

- ClinTrak® – a proprietary, feature-rich, and fully customizable Clinical Trial Management System that provides real-time access to all patient and study data, critical for rapidly enrolling fast-paced vaccine trials
- Full-service approach provides cross-collaboration and insights from various medical perspectives
- Integrated global central lab with safety, immunogenicity, and biomarker validation and analysis

IN-HOUSE EXPERTISE

The Medpace model gives Sponsors the advantage of early and ongoing insight and guidance from therapeutic experts throughout trial design and execution. Our highly experienced medical doctors work closely with our regulatory and operations experts to provide strategic direction for study design and planning, train operational staff, work with Investigators, provide medical monitoring, and meet with regulatory agencies. They are embedded throughout every study, providing greater depth and the ability to tackle complex and challenging diseases.

Additionally, our operational teams, including clinical trial managers and project coordinators, are therapeutically aligned to facilitate specialized training to sites and help mitigate challenges. Operationally, Medpace has a proven track record of rapid study start-up, successful recruitment and retention, high quality site monitoring and oversight, and proactive risk mitigation. With turnover rates that are lower than the industry standard, teams are often consistent from project initiation to completion, adding continuity and efficiency to the study.

VACCINE EXPERIENCE

The Medpace infectious diseases and vaccine team has the global experience in addressing considerations that enable us to support vaccine clinical trials across a wide range of vaccine types and populations. Medpace medical and operational vaccine experts have broad experience across indications, including but not limited to:

- Respiratory Syncytial Virus (RSV)
- Human Papillomavirus (HPV)
- Herpes Simplex Virus (HSV)
- Cytomegalovirus (CMV)
- Meningococcal
- Malaria
- Influenza
- COVID-19
- Pneumococcal
- C. diff
- Shingles
- Hepatitis-B
- West Nile virus
- Anthrax
- Dengue
- Ebola
- Measles, Mumps, and Rubella (MMR)

REAL-TIME ACCESS TO PATIENT AND STUDY DATA

As part of the full-service model, Medpace offers a proprietary Clinical Trial Management System, ClinTrak®, with leading edge technology to inform decision making, drive efficiencies and keep studies on track. ClinTrak uses a common data platform and infrastructure allowing for study optimization and real-time access to patient and study data, critical for rapidly enrolling fast-paced vaccine trials.

ORGANIC GROWTH

Medpace's history of purposeful, organic growth provides Sponsors consistency in leadership and deep institutional experience. Over decades, we've systematically added specialized medical, regulatory, and operational experts, and refined and enhanced custom-built technologies and processes to best serve the needs of our clients. The result is a culture built on quality that has not been disrupted by acquisitions, and that delivers ongoing efficiencies and stability.

DATA INTEGRITY UNIT

A specialized Data Integrity Unit is dedicated to collaborating with the clinical team and ensuring the protocol is maximally operationalized to collect appropriate microbiological, immunogenicity, and biomarker data to evaluate study outcomes. The team will also liaise with local and central labs as well as provide real-time review of study diagnostic and laboratory data to monitor protocol testing and identify trends or issues. The Data Integrity Unit works closely in collaboration with the Medpace Data Management team, on case report form design and data cleaning to ensure the quality and scientific integrity of the data are satisfactory.