MEDPACE

ACCELERATE CLINICAL DEVELOPMENT IN INFECTIOUS DISEASES

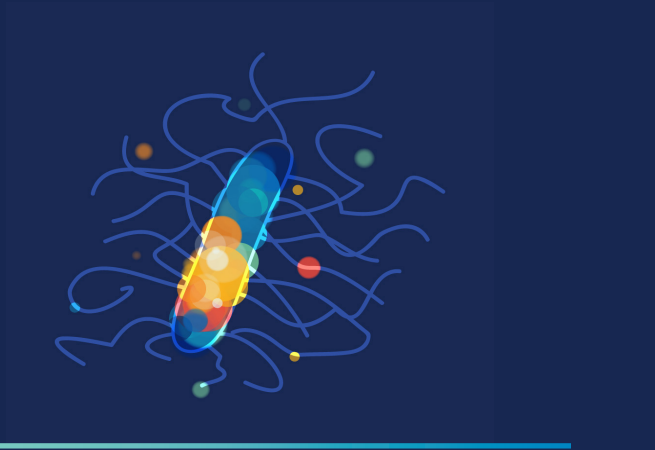
Finding effective treatments and vaccines for viral, bacterial, and fungal infections are vital for improving global health. To streamline your clinical development, Medpace offers medical and regulatory experts, therapeutic experience, and the disciplined processes, site relationships, and technologies required to execute even the most difficult studies.

FULL-SERVICE ADVANTAGE

Medpace supports our sponsors through specialized expertise in the design and management of anti-infective programs that maximize a drug candidate's probability of success. Utilizing a one-stop approach to drug development, Medpace keeps your programs on course. We combine efficient clinical trial management, comprehensive regulatory consulting, and innovative technologies to execute at the highest level.

INTEGRATED PROJECT TEAMS

Medpace and its Infectious Diseases team have broad experience conducting anti-infective clinical trials spanning adult and pediatric populations. Our physicians and professional staff understand the complexities of ID 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 clinical trial that we conduct.



EXPERTS

- Seasoned medical, regulatory and clinical project teams with extensive experience designing and conducting infectious disease and vaccine clinical trials
- Led by noted experts in infectious diseases & vaccines, Medpace medical experts are deeply embedded in your trials from protocol design through submission
- Expertise to secure government and non-dilutive funding such as BARDA, NIH, and Wellcome Trust

EXPERIENCE

- Broad experience in anti-infective drug development, including antivirals, antibiotics, antifungals, biologics, and vaccines
- Spans adult and pediatric populations
- Phase I - IV clinical development experience including designing and executing first in man PK SAD/MAD studies, Phase II studies with complex PK/PD analyses, and large Phase III global trials
- In the last 5 years, involved in over 70% of antibacterial approvals in the US and over 30% of all non-parasitic anti-infectives approvals

EXECUTION

- Full-service approach to drug development
- Strong relationships with key industry investigative sites expedites study start-up, patient recruitment, and query resolution
- Ongoing interactions with FDA's anti-infective division
- Partnering relationships with key specialty infectious disease laboratories
- Powerful, web-based Clinical Trial Management technology platform

STRONG LAB PARTNERSHIPS

ID trials require sophisticated and specialized testing and lab services. We are partnered with key specialty laboratories to provide specific state-of-the art microbiology and molecular infectious diseases capabilities to complement services already provided by Medpace Central Laboratories. These partnerships include specialists in microbiology, virology and immunology, and PK/PD modeling.

RECENT EXPERIENCE IN INFECTIOUS DISEASES & VACCINES

- HIV
- Hepatitis B virus
- Hepatitis C virus
- RSV Bronchiolitis Obliterans Syndrome
- Acute bacterial skin and skin structure infections
- Acute and chronic bronchitis
- Community-acquired pneumonia
- Coronavirus Disease 2019 (COVID-19)
- Hospital-acquired pneumonia and ventilator associated pneumonia
- Complicated intra-abdominal infections
- Urinary tract infections (uncomplicated and complicated)
- Sexually transmitted diseases (including HSV and HPV)
- Bacterial endocarditis
- Bacterial conjunctivitis
- Severe whooping cough (Bordetella pertussis)
- Clostridium Difficile Infection (CDI)
- Shiga-toxin producing E. coli and Hemolytic Uremic Syndrome
- Multi-drug resistant (MDR) pathogens
- Staphylococcus aureus including MRSA
- Fungal infections
- Tuberculosis

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, diagnostic, 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.

COMPREHENSIVE SERVICES

- Therapeutically-focused consulting services for protocol and project development
- Study start-up
- Investigative site selection and management
- Regulatory submissions
- Medical writing/safety/quality assurance
- Clinical monitoring
- Pharmacovigilance
- Clinical packaging and supplies
- Data management and biostatistics
- EDC/IVRS through Clintrak®, a proprietary, web-based decision support system
- Early-Phase services through Medpace Phase I Unit and Bioanalytical Labs
- Lab services through Medpace Central Labs

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.

MAKING THE COMPLEX SEAMLESS®