MEDPACE

RESPIRATORY CLINICAL DEVELOPMENT

Medpace's expertise and consistent track record of success as a full-service CRO ensures the flexibility required for the unique needs of respiratory clinical research.

Our collaborative team of experts understand the complexities of respiratory 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.

Medpace has the global experience to support Phase I-IV clinical trials across a wide range of indications, including but not limited to:

- Asthma
- Chronic Obstructive Pulmonary Disease (COPD)
- Bronchiectasis
- Emphysema
- Interstitial Lung Disease
- Idiopathic Pulmonary Fibrosis (IPF)
- Sarcoidosis
- Cystic fibrosis
- Alpha-1 Antitrypsin Deficiency (AATD)
- Pulmonary Embolism
- Pulmonary Hypertension
- Bacterial and Viral Pneumonia
- Acute Respiratory Distress Syndrome (ARDS)
- Obstructive Sleep Apnea
- Lung Cancer
- Mesothelioma

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

EXPERTS

- A collaborative cross-functional team of medical, regulatory, and clinical experts with extensive experience designing and conducting respiratory clinical trials
- In-house medical experts, including pulmonologists, clinical immunologists, and allergist, that 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 across a wide range of indications
- Therapeutically-aligned functional teams with a deep understanding of the complexities of respiratory trials
- Strong relationships with investigative sites and key opinion leaders (KOLs)

EXECUTION

- Full-service approach provides cross-collaboration and insights from various medical perspectives
- A proprietary, feature-rich, and fully customizable Clinical Trial Management System to inform decision making, drive efficiencies and keep your study on track
- Recruitment expertise in relevant patient populations
- Integrated global central lab with safety and biomarker validation and analysis
- Integrated imaging and ECG core lab with an end-to-end suite of global imaging services

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, including pulmonologists, clinical immunologists, and allergists 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.

INTEGRATED FOR EFFICIENCY

Integrating core clinical trial services delivers an efficient and streamlined execution. Medpace offers comprehensive and fully-integrated laboratory services including global Central Laboratories, Bioanalytical Laboratory, Imaging and ECG Core Lab, as well as a Phase I Unit.

As part of the full-service model, Medpace offers ClinTrak®, a proprietary, feature-rich, and fully customizable Clinical Trial Management System to inform decision making, drive efficiencies and keep your study on track. ClinTrak uses a common data platform and infrastructure allowing for study optimization and real-time access with a single login for critical study data, tracking, interpreting, and communicating information in a timely, secure, and cost-effective manner.

OPTIMIZED SITE SELECTION

A data-driven, risk-assessed feasibility and recruitment strategy coupled with an expert, dedicated patient recruitment and retention team ensures expedited enrollment and reduced patient dropouts. Medpace's IntelliPACE® model synthesizes data from internal and external data sources to guide the selection of the best countries and sites for study participation. Site selection is further enhanced by established relationships with individual sites and site networks.

PATIENT-CENTERED APPROACH

Respiratory patients face unique obstacles in their daily lives and treatments. Minimizing patient burden is a key component in recruiting a committed group of patients for these programs. Medpace places patients at the center of a trial to increase awareness and reach enrollment goals while helping yield successful outcomes in terms of study design, participation, adherence, satisfaction, and data collection.

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®