MEDPACE®

EARLY PHASE CLINICAL DEVELOPMENT

Early phase clinical development establishes the foundation for every downstream development decision. Medpace partners with Sponsors at these early stages to design, execute, and interpret early phase studies generating high-quality, decision-ready, evidence-based data.

As a therapeutically focused, fully integrated CRO, Medpace combines medical leadership, translational science, bioanalysis, and operational execution under one model – enabling faster timelines, tighter data integration, and clearer insights informing later-phase program success.

INTEGRATED EARLY PHASE CAPABILITIES

Medpace delivers end-to-end early phase development support, including:

- First-in-Human (FIH)
- Single Ascending Dose (SAD) / Multiple Ascending Dose (MAD)
- Dose escalation, multiple cohort, and adaptive designs
- Single and multiple dose studies
- PK/PD and translational modeling
- Food effect studies
- Drug–drug interaction (DDI)
- Bioavailability / Bioequivalence
- Thorough QT / QTc
- Phase IIa and proof-of-concept
- Device and diagnostic studies

MAKING THE COMPLEX

SEAMLESS®

EXPERTS

- Embedded and therapeutically aligned medical, regulatory, and operations teams work as partners engaged from protocol design through database lock
- Scientific leadership spanning clinical pharmacology, PK/PD, bioanalysis, and translational medicine
- Dedicated Medpace Phase I Unit staff experienced in volunteer recruitment, screening, and inpatient study conduct in early development study designs

EXPERIENCE

- Extensive global early phase experience spanning first-in-human through Phase IIa proof-of-concept studies
- Proven execution of complex study designs including SAD/MAD, adaptive dose escalation, food effect, DDI, and QT/QTc studies providing invaluable early efficacy signals
- Deep understanding of global regulatory requirements impacting early phase development, including controlled substances and complex safety monitoring

EXECUTION

- Extensive recruitment infrastructure and successful strategies to fulfill study cohort and enrollment needs
- Integrated clinical, bioanalytical, and central laboratory operations to streamline sample handling, data flow, and decision-making
- Technology-enabled processes supporting study conduct, safety oversight, and data integrity across early phase programs
- Purpose-built Medpace Phase I Unit with inpatient and outpatient capabilities to support a broad range of early phase studies

ESTABLISHED GLOBAL SITE NETWORK

Medpace offers Sponsors access to a global network of trusted, high-performing site networks that from our experience are capable of supporting specialized early phase populations and study designs. With a deeply embedded global footprint, this network has proven experience delivering rapid study startup, high-quality data, and reliable throughput enrollment.

PLACEBO RESPONSE & DATA INTEGRITY

Medpace applies structured approaches to mitigate placebo response and variability, reducing risk in early phase studies, including:

- Comprehensive site staff training on participant interaction
- Participant focused education on study requirements and placebo use
- Processes designed to encourage accurate, objective feedback

MEDPACE BIOANALYTICAL LAB

Leveraging state-of-the-art facilities, techniques, and instrumentation, our team of experts has experience in a broad range of small and large molecule bioanalytical and biomarker support.

MEDPACE CENTRAL LABS

Medpace's central laboratories provide global lab services across all stages of clinical development, offering an extensive biomarker menu supported by advanced laboratory techniques. With wholly owned facilities in the United States, Europe, China, and Singapore, our central labs have the technology and expertise to support global studies, assist with regulatory requirements, and deliver custom solutions for any need.

MEDPACE PHASE I UNIT

Located on our dedicated research campus in Cincinnati, Ohio – and fully embedded within Medpace's global, full-service CRO model – the Medpace Phase I Unit is purpose-built to support today's most demanding early phase studies.

Features of this state-of-the-art facility include:

- Four independent inpatient units, designed to accommodate a broad range of clinical pharmacology studies
- 85-bed capacity, including semi-private suites and patient-centric design to enhance retention and protocol continuity
- A dedicated, licensed Investigational Drug Services Pharmacy, fully equipped for complex investigational products
- On-campus access to central labs, imaging, biostatistics, and medical writing

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.

WE CAN'T SIMPLIFY CLINICAL DEVELOPMENT – BUT WE CAN EXECUTE IT SEAMLESSLY.

MAKING THE COMPLEX SEAMLESS®