MEDPACE®

ENDOCRINE & METABOLIC CLINICAL DEVELOPMENT

Since its inception in 1992, the advancement of novel therapies for endocrine and metabolic diseases and disorders has been a primary therapeutic focus for Medpace. Led by a global team of medical, operational, and regulatory experts, our company has helped pioneer mainstays of therapy that have revolutionized the care and quality of life for patients. This experience spans a broad array of trial designs, product classes, and disease endpoints and includes all phases of clinical research.

Therapeutic Modalities Across a Multitude of Common and Rare Indications:

- Small Molecules
- Biologics
- Medical Devices
- Cell and Gene Therapies

INTEGRATED EFFICIENCY

A core differentiator from other CROs is the heightened efficiencies that come from our full-service and integrated model including central laboratories, a bioanalytical lab, an imaging core lab, ECG core lab and a Phase I unit. For endocrine and metabolic studies, the integration of all of these services provides an accountable and seamless platform that increases quality and speed while significantly reducing a Sponsor's need for duplicate management oversight.





EXPERTS

- Accomplished, in-house medical doctors
- Cross-functional and collaborative medical teams in related therapeutic disciplines
- Advanced Nurse Practitioners with patient and site perspectives
- Highly-trained clinical operations teams and empowered problem-solvers
- Regulatory experts experienced in global and regional requirements

EXPERIENCE

- Conducted hundreds of trials across all phases of development including large endpoint/outcome studies
- Spanning drug, device and combination products
- Navigated multi-country regulations and requirements across the globe
- Supported over 20 NDAs in which Medpace had significant involvement
- Collaborations with Academic Research Organizations
- Success recruiting in difficult to recruit populations
- Specialized experience including rare diseases and cell and gene therapies

EXECUTION

- Close working relationships with investigators and sites
- Proprietary patient recruitment and retention platform including data-driven feasibility
- One of the most extensive selections of metabolic biomarkers
- High levels of efficiency and collaboration through our fully integrated services
- Clintrak® study management tool provides IVRS/IWRS, study, data, laboratory, and image management, as well as endpoint adjudication and ePRO/eDiary

MEDICAL, OPERATIONAL & REGULATORY EXPERTS WORKING COLLABORATIVELY

Our proficient and experienced team members work closely throughout a study to ensure high levels of quality and efficiency.

- Experienced medical doctors provide strategic direction for study design, train operational staff, work with Investigators, provide medical monitoring, and meet with regulatory agencies, while advanced nurse practitioners provide support with their unique patient and site perspectives to help streamline and optimize studies. Our medical experts are embedded throughout every study.
- 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.
- Our experts are trained to guide you through regulatory and competent authority approval processes to accelerate pathway approvals.

SUPPORTING CAPABILITIES

Global Central Labs

Founded as a reference lab for metabolic and lipid modifying therapies, Medpace's central laboratories are recognized as a global leader for our deep expertise and array of biomarkers and services in endocrine and metabolic clinical development — from discovery and proof of concept through large, long term global trials. CAP accredited labs are located in the US, Belgium, Singapore and China.

Imaging Core Lab

Medpace provides comprehensive imaging expertise to ensure that imaging components are seamlessly integrated into the clinical trial. We support imaging analysis for metabolic disorders such as diabetes, obesity, non-alcoholic fatty liver disease (NAFLD), and non-alcoholic steatohepatitis (NASH). Our metabolic imaging endpoint measurements include hepatic fat fraction, and hepatic fibrosis.

ECG Core Lab

Our cardiac safety solutions for endocrine and metabolic disorders include TQT studies, ambulatory ECG monitoring, ambulatory blood pressure monitoring and adjudication expertise.

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.

Phase I Unit

Located on the same campus as the CRO, bioanalytical lab and central lab in the US, our Phase I unit actively nurtures and expands its database of special patient populations, including diabetic populations and patients with a BMI > 30.

Medical Device and Drug/Device Combination

Within Medpace, a group of operations and regulatory professionals specialize in the design and conduct of medical device trials. Our endocrine and metabolic experience spans glucose monitoring devices, insulin delivery devices, gastric stimulation, and gastric volume restrictive devices (balloon devices and organic, expandable capsules).

With both drug and device expertise, our collaborative team understands the nuances from both perspectives. Our experience with large-scale multinational trial programs, (including emerging markets), and our broad compound experience for Type 1 and Type 2 diabetes, major obesity programs, hypercholesterolemia and mixed dyslipidemia provides a strong backdrop for sponsors with drug-device combination products.

MAKING THE COMPLEX SEAMLESS®

