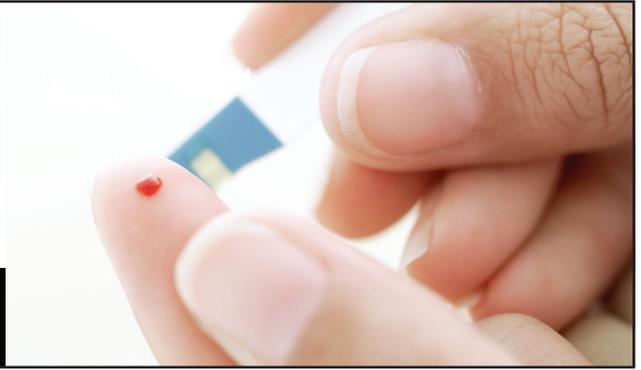


M E D P A C E

METABOLIC/ENDOCRINE CLINICAL DEVELOPMENT

Experts. Experience. Execution.

Discover the **POWER OF X**



The Power of X in Metabolic/Endocrine Clinical Development

Experts:

- Founded by Dr. August Troendle, former Medical Review Officer in the Division of Metabolism and Endocrinology Drug Products at the FDA
- Led by metabolic and endocrinology experts, Medpace has extensive experience in all aspects of clinical research for drug and device in this area
- Seasoned, collaborative project teams with proven success

Experience:

- 300 completed projects in metabolic area
- 20 NDAs in metabolism for which Medpace had significant involvement in development program
- Large-scale multinational trial programs - emerging markets - 35 countries
- Experience with endpoint/outcomes trials
- Collaborations with Academic Research Organizations
- Drug, device and combination products

Execution:

- Well-profiled network of sites on global scale
- In-depth feasibility process leveraging global experience and site relationships
- Clinical and regulatory advisory services
- Integrated central lab, ECG core lab and clinical pharmacology unit for seamless clinical development
- Strong relationships with key industry investigative sites and KOLs

The Medpace Advantage: Specialized Clinical Development in Drug and Device Projects

Since its inception in 1992, the advancement of novel therapies for metabolic and endocrine disorders has been a primary therapeutic focus for Medpace. Led by an international team of medical and regulatory experts, our company has helped pioneer mainstays of therapy that have revolutionized the care and quality of life of patients. This experience spans a broad array of trial designs, product classes, and disease endpoints and includes all phases of clinical research. The Medpace team's years of experience conducting metabolic and endocrine studies is unmatched by any other Clinical Research Organization.

- Unsurpassed regulatory experience in chronic metabolic and endocrine disorders
- Operational staff with proven track record of rapid study start-up, successful recruitment and retention, high quality site monitoring and oversight, and proactive risk mitigation
- One of the most extensive selections of metabolic biomarkers for clinical trials via Medpace Central Laboratories (US, Europe, China and Singapore)
- A database of special phase 1 patient populations, including diabetic populations and patients with a BMI > 30, as well as specialized testing such as glucose clamp studies via the Medpace Clinical Pharmacology Unit
- In-house cardiac safety, thorough QT, and adjudication expertise supported by the Medpace Cardiovascular Core Lab

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Metabolic/Endocrine Experience by Compound

- PCSK9 inhibitors
- SGLT-2 inhibitors
- Insulins: concentrated, inhaled, rapid-acting, long-acting
- GLP-1 agonists
- Diabetes management apps
- Appetite suppressants
- Kisspeptin modulators
- Omega-3s
- Anti-sense oligonucleotides
- Glucagon antagonists
- Amylin analogs
- Autologous stem cell therapies
- Gene therapies
- Glucometers
- Low-calorie sweeteners
- GIP receptor agonists
- Ghrelin agonists
- Osteogenesis modulators
- DPPIV inhibitors
- Novel glucagons
- Novel octreotides
- Novel testosterone
- Novel growth hormones
- Thyroid receptor agonists
- Glycation assays
- Cholesterol absorption inhibitors
- ACE inhibitors
- TZDs
- Fibrates
- Statins
- Biguanides

Clinical Pharmacology Highlights

- Experience includes 140+ Phase I studies in normal healthy volunteer and patient populations including diabetes, CAD, and obesity
- 60,000 square foot facility centrally located on our main research campus in Cincinnati adjacent to the CRO and laboratories
- Dedicated PIs, pharmacists, and experienced clinical staff including 22 full time BSN prepared nurses
- An FDA audit in February resulted in no 483s at the close-out visit

Feasibility – Accelerating Patient Recruitment and Optimized Patient Retention

Medpace has a stellar record for patient recruitment and site relationships, particularly in the metabolic/endocrine arena. As a result of 25 years of involvement in the field, Medpace has established many long-term relationships with clinical sites worldwide that specialize in conducting these studies. The investigators, many of whom are key opinion leaders, are well known to the Medpace Medical Monitors, having worked with Medpace for many years. These relationships facilitate more accurate feasibility and greater involvement of the Investigators in the conduct of the study, which translates into better recruitment and study management.

Medical Device

Within Medpace, there is a group of operations professionals specifically dedicated to the design and conduct of medical device trials. Our metabolic and endocrine experience spans:

- Glucose monitoring devices
- Insulin delivery devices
- Gastric stimulation
- Gastric volume restrictive devices (balloon devices and organic, expandable capsules)

Drug/Device Combination

Medpace brings together its medical and regulatory experts into a collaborative team that understands the nuances from both the drug and device 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.

Who We Are

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. Headquartered in Cincinnati, Ohio, Medpace employs approximately 2,500 people across 35 countries.

M E D P A C E

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medpace.com | info@medpace.com

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Europe

Latin America

Asia

Africa

Middle East

Australia