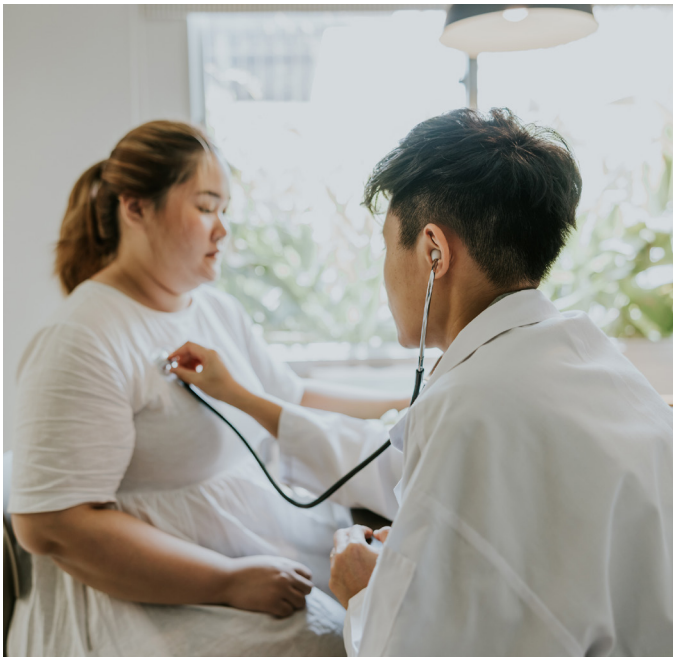
MEDPACE

OBESITY CLINICAL DEVELOPMENT

With decades of phase I-IV metabolic experience and access to in-house and external data streams, Medpace supports the development and execution of global obesity trials. Medpace has medical, operations, and regulatory staff who understand the complexities of obesity trials from the perspective of the Sponsor, the patients, the clinical investigator, the scientific leader, and the reviewer at the regulatory agencies. Our matured relationships with global thought leaders, investigative sites, the Medpace global 'flagship' metabolic site network, and patient advocacy groups, as well as knowledge of effective patient retention strategies, ensure efficient and quality patient enrollment and retention which is key to the success of these programs.

In addition to therapeutically specialized, full-service CRO offerings, Medpace provides comprehensive and fully integrated global central lab services, a bioanalytical lab, an imaging core lab, an ECG core lab, and a Phase I unit. The built-in collaboration and efficiencies of working with a single vendor facilitates a streamlined strategy for executing obesity trials of all sizes and scope.



MAKING THE COMPLEX

SEAMLESS®

EXPERTS

- Team of accomplished, in-house medical experts
- Cross-functional and collaborative medical teams in related therapeutic disciplines
- Advanced Nurse Practitioners provide an additional layer of expertise, including patient and site perspectives
- Highly-trained clinical operations teams and empowered problem-solvers
- Regulatory experts experienced in global and regional requirements

EXPERIENCE

- Managed a pivotal Phase 3 obesity program and NDA submission for the approved treatment
- Personal relationships with world-renowned KOLs and site staff that position your study/program with some of the fastest start-up timelines and study completion goals
- Validated test menu including over 45 obesity-related assays

EXECUTION

- Current and active relationships across nearly 9,000 global sites for metabolic research
- Data-driven feasibility through our IntelliPACE® patient recruitment and retention platform
- 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

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. Key sites across the globe have earned the designation of a 'Flagship Site' and have a history of partnering with Medpace for timely, high-quality outcomes.

EXPEDITING ENROLLMENT & IMPROVING PATIENT RETENTION

Study enrollment efforts are centralized and streamlined through our in-house patient recruitment and retention teams. We ensure that patients are supported throughout their clinical trial experience by focusing on education, comfort and convenience, and providing technology to support participation.

A well-known challenge in the clinical development of anti-obesity agents is the potential high drop-out rate, primarily attributed to: perceived absence of effect in regard to weight loss, poor tolerability of study drug/study requirements, and access to alternative treatment options. Our experience and knowledge of key mitigation strategies to address these retention challenges in obesity trials enable us to reduce drop-outs to keep studies on track and ensure the highest quality of endpoints.

INTEGRATED CENTRAL LABORATORY

Our validated test menu includes over 45 obesity-related assays, including HbA1c, fasting glucose and insulin, GH, IGF-1, TSH, and other biomarkers of insulin resistance (e.g. HOMA-IR and proinsulin/insulin ratio). Our in-house experts can help you determine the best biomarkers, the right analytical method and appropriate regulatory approach for your compound.

FULL- SERVICE CLINICAL DEVELOPMENT

Medpace is a global full-service clinical research organization providing Phase I-IV core development services for drug, biologic, and device programs. With medical and regulatory expertise in multiple therapeutic specialties. Medpace has assembled therapeutically focused teams to execute at every level of the company's operations, providing complete and seamless drug and device development services.

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