



MEDPACE ADVANTAGE FOR OBESITY STUDIES

Experts. Experience. Execution.

Medpace is your best choice for a partner with deep obesity experience. Medpace has a proven track record conducting some of the industry's largest obesity studies including a large Phase III pivotal study for a current commercial product.

The Market for Obesity Therapeutics

Obesity is a growing health crisis affecting both children and adults and has been described by the World Health Organization as an escalating global epidemic. In USA, more than two-thirds (68.8%) of adults, over the age of 20 years, are either obese or overweight.¹ Obesity is now considered a chronic disease by the American Association of Clinical Endocrinologists (AACE), which supports the use of pharmacotherapy in patients who are overweight, especially those with obesity-related co-morbidities such as Type II Diabetes Mellitus (T2DM), hypertension, dyslipidaemias and cardiovascular disease.² The public health burden of obesity is huge, with one estimate showing that \$190.2 billion is spent in USA on obesity-related health care, which represents 20.6% of national health care expenditures³.

Despite the huge public health burden related to obesity – there are few marketed pharmaceutical products to treat the disease. Medpace prides itself as a CRO that has been involved in several pivotal Phase III studies involving anti-obesity products, which have led to marketing approval. Medpace has robust experience covering early development and late phase obesity studies, including a wealth of scientific and medical knowledge, operational experience, central lab support, core imaging, and a state of the art Clinical Pharmacology - Phase I unit.

Why choose Medpace for Obesity Studies?

- Scientifically-driven approach takes advantage of our deep clinical trial experience and scientific expertise in endocrinology and metabolic disease.
- Full service capabilities includes Central Lab and Core Imaging Lab, and Clinical Pharmacology Unit
- Experience in conducting a successful Obesity program from Phase I-III and NDA support, including Central Lab, Imaging, and Drug Safety and Pharmacovigilance services including clinical endpoint adjudication and post-marketing safety teams
- Existing investigative site relationships with local KOLs
- Strong operational experience in large Phase III Obesity Studies (7,000 Patients at 138 US Sites)

Medpace Central Laboratories

Medpace Central Labs have long been a leader in conducting large, global endocrinology studies. With laboratories in the US, Europe, China and Singapore, Medpace Central Labs has the global reach and capabilities to conduct endocrine/metabolic studies in concert with Medpace CRO or as a standalone service.

Featuring fully-owned state-of-the-art instrumentation and assay protocols, every Medpace Central Laboratories location is fully accredited by the College of American Pathologists (CAP), all are independently certified, participate and meet CDC Part III lipid standardization, all are Level 1 NGSP for HbA1c and the USA lab is CLIA Certified.

Biomarkers and Specialty Testing

The successful execution of a biomarker strategy requires a flexible approach. We offer multiple biomarkers, using different techniques and platforms providing results that enable patient stratification and improve prediction of drug efficacy and safety.

Medpace Imaging Core Lab (MICL)

Medpace Imaging Core Lab provides holistic central imaging services including site assessment, qualification and training, recording equipment, provisioning, image processing (blinding and quality control) and expert evaluation. Independent Centralized Image Readers

Medpace Imaging Core Lab provides blinded central readings from a defined pool of more than 200 board certified, sub-speciality trained radiologists, cardiologists, and other specialists.

Our readers have extensive clinical trial experience with cardiovascular and endocrine, diseases, as well as interventional and medical device studies, utilizing imaging modalities such as 3D volumetric analysis, ultrasound, DEXA, MRI, angiography, endoscopy, and photography.

Medpace Clinical Pharmacology Unit (CPU)

The 60,000 sq. ft. Medpace Phase I unit, located in Cincinnati Ohio is adjacent to the CRO and Laboratories providing a full service approach to Obesity studies.

CPU Highlights:

- Experience includes 140+ Phase I studies in normal healthy volunteer and patient populations including diabetes, CAD, and obesity
- Dedicated PIs, pharmacists, and experienced clinical staff including 22 full time BSN prepared nurses
- An FDA audit in February, 2017 resulted in no 483s at the close-out visit.

Drug Safety and Pharmacovigilance Services

Our Clinical Safety, Clinical Endpoint Adjudication, and Postmarketing Safety teams offer global capabilities with offices and personnel in the United States and the European Union (EU).

Pharmacovigilance Highlights:

- Collection, evaluation, analysis, and reporting of safety information, including serious adverse events, unanticipated adverse device effects, and other significant safety events
- Coding (MedDRA, WHO Drug) of adverse event information
- Assessment and evaluation of reportability and submission of reportable events to global regulatory authorities
- EudraVigilance reporting and e-reporting in the EU
- Preparation and submission of annual safety reports, six monthly line listings, and periodic reports to global regulatory authorities

Recruitment and Global Site Relationships

Medpace has strong relationships with established Investigator contacts in Endocrinology. The ability to recruit and retain study participants for obesity studies requires a comprehensive site feasibility assessment, a well-designed study, and established relationships with key opinion leaders and principal investigators.

Obesity Experience Summary

| STUDY DESCRIPTION | SITES | PATIENTS | MEDPACE SERVICES | GEOGRAPHIC REACH |
|--------------------|-------|----------|--|------------------|
| Phase I, Obesity | 1 | 48 | Biostatistics, Clinical Monitoring, Clinical Safety, Data Management, MCCL, Medical Writing, Quality Assurance, Study Documents | US |
| Phase N/A, Obesity | 1 | 250 | Clinical Monitoring, Services | US |
| Phase IV, Obesity | 4 | 42 | Full Service, MCCL | US |
| Phase IV, Obesity | 12 | 242 | Biostatistics, Clinical Monitoring, Clinical Safety, Data Management, Interactive Voice Response System (IVRS), Project Management | US |
| Phase IIb, Obesity | 15 | 70 | Clinical Monitoring, Project Management | US |
| Phase IV, Obesity | 20 | 200 | Full Service, MCCL, Study Documents | US |
| Phase, Obesity | 23 | 168 | Data Management | US |
| Phase, Obesity | 24 | 400 | Data Management | US |
| Phase, Obesity | 25 | 300 | Data Management | US |
| Phase III, Obesity | 36 | 676 | Biostatistics, Clinical Monitoring, Data Management, Laboratory Tests, Medical Writing, Project Management, Start-up Services | US |
| Phase III, Obesity | 45 | 4,563 | Full Service | US |
| Phase III, Obesity | 93 | 2,487 | Full Service, Laboratory Tests | US |

Endocrine and Metabolic Therapeutic Experience

We have significant experience in the Endocrinology and Metabolic therapeutic disease area, and have conducted >300 studies in the metabolic area (Phase I-IV) including 20 NDAs in metabolism for which Medpace had significant involvement in development program.

Scientifically-driven Expertise in Metabolic Studies

The Medpace global physicians are noted in their fields of specialty. Obesity studies require scientifically-driven study design and execution in the CRO and lab support to ensure precision in conduct of the study.

Phillippa Miranda, MD

Senior Medical Director

Dr. Miranda received her M.D. from Duke University School of Medicine and completed her residency in Internal Medicine and her fellowship in Endocrinology at Duke. She served on the faculty in the Division of Endocrinology at Duke University Health System for five years prior to transitioning to industry. Dr. Miranda is board certified in Endocrinology, Diabetes, and Metabolism. Her therapeutic expertise covers a wide range of metabolic indications with significant medical monitoring experience in the areas of type 2 diabetes, type 1 diabetes, and obesity. Dr. Miranda has over seven years of experience conducting clinical research studies with a large CRO and is well versed in the conduct of Phase 2 and 3 studies in endocrinology.

Douglas Lee MB BCh, MRCP, MBA

Senior Medical Director

Dr. Lee is an experienced drug developer with about 20 years of experience in both clinical medicine and drug development, with therapeutic expertise in Endocrinology and Metabolic Disease. Dr. Lee is currently a clinical reviewer for the journal Diabetes, Obesity and Metabolism. Prior to joining Medpace, Dr. Lee was the Global Senior Medical Director for a large pharmaceutical company where he designed, oversaw and executed global development plans involving early and late phase assets. In 2012 -13, he led a team that gained Marketing Authorization Approval (MAA) for 3 Endocrinology and Metabolic products, under the European Centralized Procedure. Dr. Lee received his Bachelor of Medicine, Bachelor of Surgery at the Queens University Medical School in the United Kingdom (UK) and achieved his Membership of the Royal College of Physicians in UK. He also earned his MBA from the Imperial College London in 2013.

Alicia Weeks, MD*Medical Director*

Alicia Weeks is an experienced Clinical Endocrinologist with a former academic clinical practice and translational research experience in Type 2 Diabetes. As a Medical Director at Medpace, she provides medical management and expertise to all phases of studies and clinical trials, as well as assists with new business development through participation in proposal and Sponsor meetings. Dr. Weeks gained experience from a dual appointment as a clinical instructor at the University of Wisconsin Hospital & Clinics and as a Research Fellow at the William S. Middleton Memorial Veterans Hospital after earning her medical degree from the Wright State University Boonshoft School of Medicine. Dr. Weeks completed her residency at the Kettering Medical Center and an endocrinology fellowship at the University of Wisconsin. There she was awarded the Dickie Research Award for her significant research contribution toward advancing the field of medicine.

Gretchen Williamson, MD, FAAP*Medical Director*

Dr. Williamson completed residency training at Penn State Hershey Medical Center and has post-graduate experience in pediatric endocrinology from Cincinnati Children's Hospital. She has clinical research experience in diabetes, hypercholesterolemia, hypertriglyceridemia, and multiple orphan indications (including familial chylomicronemia). She also has protocol development experience for numerous therapeutic areas, including rheumatoid arthritis, hypogonadism, pancreatic insufficiency, growth hormone deficiency, and stem cell therapies.

About Medpace

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.

References

- 1) NIDDK Figures. <https://www.niddk.nih.gov/health-information/health-statistics/overweight-obesity>
- 2) Cawley J, Meyerhoefer C. The medical care costs of obesity: an instrumental variables approach. *J Health Econ.* 2012; 31:219-30.
- 3) American Association of Clinical Endocrinologists (AACE) Obesity Guidelines. <https://www.aace.com/files/guidelines/ObesityAlgorithm.pdf>