



THE POWER OF X Type 2 Diabetes Mellitus

Experts. Experience. Execution.

Medpace Strategy for Type 2 Diabetes Mellitus (T2DM) Studies

Since its inception in 1992, Medpace has conducted hundreds of metabolic and endocrine studies around the globe including T2DM programs. Medpace specialty teams with noted medical experts, highly experienced clinical trial management teams, central labs, and core imaging labs can accelerate your next study.

The Market for T2DM Therapeutics

According to National Institute of Diabetes and Digestive and Kidney Diseases, T2DM is a long term metabolic disorder that is characterized by high blood sugar, insulin resistance, and relative lack of insulin. The condition consists of an array of dysfunctions characterized by hyperglycemia and resulting from the combination of resistance to insulin action, inadequate insulin secretion, and excessive or inappropriate glucagon secretion (Medscape). Rates of diabetes are increasing worldwide. The International Diabetes Federation predicts that the number of people living with diabetes will rise from 366m in 2011 to 552m by 2030. A 2011 Centers for Disease Control and Prevention (CDC) report estimated that nearly 26 million Americans have diabetes (U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2011. National diabetes fact sheet: national estimates and general information on diabetes and prediabetes in the United States, 2011). Additionally, an estimated 79 million Americans have prediabetes (Medscape).

Studies to determine the cause and treatment of T2DM are critical, given the global growth of this disease. Medpace, a global full service CRO with deep experience in metabolic studies, is a key CRO involved in T2DM studies. The Medpace model, combined with Medpace Central Labs, and Core Imaging Services combines to accelerate T2DM studies on a global platform.

Why Choose Medpace for a T2DM Study

- Scientifically-driven approach takes advantage of our deep clinical trial experience and scientific expertise in the endocrinology and metabolic disease area, and more specifically in Type II Diabetes studies
- Full service capabilities inclusive of Central Lab and Core Imaging Lab, and Clinical Pharmacology Unit
- Existing investigative site relationships with local KOLs who specialize in recruiting patients with T2DM
- Strong operational experience in running T2DM studies

Medpace Central Labs with Biomarker Services Supporting T2DM Studies

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 T2DM studies in concert with Medpace CRO or as a standalone service.

Biomarker Strategic Services

Medpace Lab's test menu includes: GH, IGF-1, TSH, HbA1c and other biomarkers of insulin resistance (eg proinsulin/insulin ratio)

Recruitment and Global Site Relationships

Medpace has strong relationships with established Investigator contacts in Diabetes Mellitus. The ability to recruit T2DM study participants requires a comprehensive site feasibility assessment, a well-designed study, and established relationships with key opinion leaders and principal investigators.

Endocrine and Metabolic Therapeutic Experience

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

Type 2 Diabetes Mellitus

Medpace Diabetes experience includes the management of over 100 diabetic trials involving over 20,000 patients globally with Type 2 Diabetes. Medpace Type 2 Diabetes trial designs have included treatment naïve patients, metformin-only patients, those with narrow HbA1c inclusion ranges, uncontrolled diabetics on routine background therapies, unique diabetic device delivery systems, glucose clamp trials, diet-controlled diabetics, elderly diabetics, mixed dyslipidemic diabetics, among others. Medpace has executed studies in subjects with Type 2 Diabetes with renal or neurologic impairment, as well as those with disease-related gastrointestinal complications. Medpace has both designed and executed full diabetic development plans, from trial start-up to NDAs and marketing submissions.

Medpace T2DM Experience Summary

STUDIES	SITES	PATIENTS	NUMBER OF STUDIES
Phase I, Type II Diabetes Mellitus	85	773	32
Phase II, Type II Diabetes Mellitus	1085	4603	26
Phase IIa, Type II Diabetes Mellitus	238	1109	13
Phase IIb, Type II Diabetes Mellitus	333	2117	8
Phase III, Type II Diabetes Mellitus	928	5803	20
Phase IIIb, Type II Diabetes Mellitus	106	762	4
Phase IV, Type II Diabetes Mellitus	871	5188	7
GrandTotal	3646	20355	110

Expertise in T2DM Studies

The Medpace global physicians are noted in their fields of specialty. T2DM studies require scientifically-driven study design and execution in the CRO and lab support to ensure precision in conduct of the study.

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

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.

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.

Prior to Dr. Williamson's work in clinical research, she had been affiliated with large, academic medical centers. Pediatric studies, across therapeutic lines, share many of the same operational considerations – study design, ethical, and regulatory issues as well as common Investigator networks. Dr. Williamson's practical clinical experience and knowledge is instrumental in her leadership of pediatric clinical trials.

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.

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.