



NAFLD/NASH CLINICAL RESEARCH

Experts. Experience. Execution.

Deep Dive: NAFLD/NASH Clinical Research

Accelerate your NAFLD/NASH study with Medpace's noted medical and regulatory experts, highly experienced clinical trial management teams, central labs, and imaging core labs

As a therapeutically-focused CRO, Medpace specializes in the design and conduct of global trials in gastroenterology and hepatology, including recent experience in NAFLD/NASH. We bring a global footprint, strategic medical, regulatory and operational leadership as well as fully integrated Central Labs and Core Imaging Services to enhance and expedite development.



Experience



Medpace has in-house physicians, imaging specialists, and operational teams with extensive experience in the advancement of pharmaceutical agents in the therapeutic areas of metabolism, hepatology, and gastroenterology including expertise in managing and executing NAFLD/NASH studies. With over eight years of experience supporting NAFLD/NASH clinical trials, Medpace can help sponsors successfully navigate the complexities and regulatory scrutiny involved with these programs. Our therapeutically-aligned teams bring a strong understanding of the key aspects of study design and patient eligibility criteria as well as the ability to manage potential challenges and logistical requirements associated with screening and enrolling this patient population. Our experience spans 14 countries, 1,300 subjects and 150 sites.

Recruitment and Global Site Relationships



With combined gastroenterology medical expertise, as well as hepatic/GI and metabolic trial experience, Medpace has strong relationships with established Investigator contacts instrumental in operationalizing NAFLD/NASH studies.

Gastrointestinal clinical studies require a unique set of expertise and relationships. The ability to recruit NAFLD/NASH study participants requires a comprehensive site feasibility assessment, a well-designed study, and established relationships with key opinion leaders and principal investigators. Patient retention over an often long treatment period with multiple and invasive assessments presents unique challenges. Finally, the ability to integrate and coordinate all of the components of a study, from early design through post-marketing studies, requires a partner with a full suite of services and operational excellence at every level.

Scientifically-Driven Clinical Research

Medpace is unique in its approach to clinical research. The Medpace model gives you the advantage of early and ongoing insight and guidance from therapeutic experts throughout trial design and execution. Our highly experienced medical doctors provide strategic direction for study design and planning, train operational staff, work with Investigators, provide medical monitoring, and meet with regulatory agencies. In addition, our medical monitors work collaboratively with our global regulatory affairs experts to provide strategic guidance into the best pathways to accelerate approvals.

Meet Our NAFLD/NASH Experts



Piotr Krzeski, MD, PhD, FFPM
Senior Medical Director,
Medical Affairs



Phillippa Miranda, MD
Vice-President, Medical Affairs



Traci Turner, MD
Executive Director, Central Labs
and Metabolic Atherosclerosis
Research Center (MARC)

Piotr Krzeski, MD, PhD, FFPM

Senior Medical Director, Medical Affairs

Dr. Piotr Krzeski is an internist with a broad background in pharmaceutical research. He has over 19 years of experience in clinical drug development, with global expertise in the design and medical oversight of clinical trials in the area of gastroenterology and hepatology including NAFLD and NASH. Dr. Krzeski completed his internal medicine training at the Gastroenterology Department at the Warsaw Postgraduate Centre in Poland. He earned his PhD in Hepatology. Dr. Krzeski is recognized in the field for his contribution to the pioneering work on standardization of central imaging in drug development.

Phillippa Miranda, MD

Vice-President, Medical Affairs

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.

Traci Turner, MD

Executive Director, Central Labs and Metabolic Atherosclerosis Research Center (MARC)

Dr. Traci Turner is board-certified in Internal Medicine, is a Diplomate with the American Board of Clinical Lipidology, and serves as the Executive Director of Medpace Reference Laboratory Operations and the Metabolic and Atherosclerosis Research Center. A native of Cincinnati, OH, she attended the University of Cincinnati and graduated with a BS in Medical Technology, where she also earned her medical degree. Dr. Turner completed her residency at University Hospital in Cincinnati, Ohio. Prior to joining Medpace, Dr. Turner's experience includes 15 years in central laboratory operations supporting the pharmaceutical industry and 7 years in practice specializing in Internal Medicine.

Medpace Global Labs Provide Safety and Biomarker Analysis



With laboratories in the US, Europe, China and Singapore, Medpace Labs has the global reach and capabilities to conduct NAFLD/NASH studies in concert with Medpace CRO or as standalone service.

Biomarker Strategic Services

Medpace Labs' test menu includes many validated biomarkers associated with NASH: cytokeratin-18 fragments (M30 and M65), apolipoprotein A1, apolipoprotein B, leptin, adiponectin, resistin, free fatty acids, ghrelin, hsCRP, interleukin-6, and tumor necrosis factor-alpha.

Medpace Labs' test menu also includes validated assays used in NASH fibrosis scores such as Fibrotest/FibroMax and ELF (Enhanced Liver Fibrosis).

Core Imaging Expertise for NAFLD/NASH Studies



High-quality image acquisition and interpretation is crucial for the success of NAFLD/NASH trials. Medpace Core Labs provides comprehensive central imaging services including site assessment, qualification and training, advanced data processing and blinded assessments. In particular, Medpace Core Labs has expertise with the implementation of various MR-Based acquisition techniques including Magnetic Resonance Spectroscopy (MRS), Proton Density Fat Fraction (PDFF; magnitude and complex) and Magnetic Resonance Elastography (MRE) to support imaging endpoints for NAFLD/NASH trials using fully regulatory-compliant platforms.

A Full-Service Approach to Clinical Research

Driven by a full-service CRO model that coordinates and integrates all services for our clients, Medpace provides an accountable, seamless, integrated and efficient platform for executing clinical research – increasing quality and speed while significantly reducing the need for duplicate management oversight. Our disciplined processes, site relationships, and technologies enable us to execute even the most complex global studies, from first-in-human through post-approval.



Medical
Affairs



Regulatory
Affairs and
Medical Writing



Clinical
Monitoring



Clinical Trial
Management



Biometrics
and Data
Sciences



Safety and
Pharmacovigilance



Quality
Assurance



Global Labs, Imaging
& Cardiovascular
Core Labs