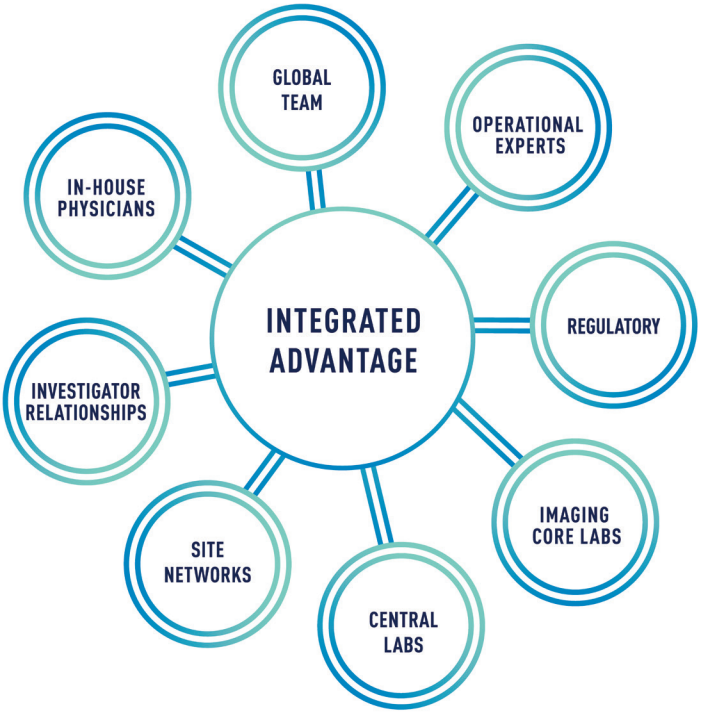
NAFLD/NASH CLINICAL RESEARCH

A FULL-SERVICE MODEL

Medpace delivers high-quality results with our proven full-service outsourcing model. As a therapeutically-focused CRO, Medpace specializes in the design and conduct of global trials in gastroenterology and hepatology, including non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH).

- NAFLD/NASH trial experience since 2010
- In-house teams experienced in successful execution of NAFLD/NASH trials with endpoints including labs, imaging, and biopsy
- Wholly-owned central lab with validated NASH soluble inflammation and fibrosis biomarkers
- Well established relationships with KOLs and high producing quality sites
- Wholly-owned imaging core lab to support NAFLD/NASH studies, ensuring imaging components such as MRE, MRI-PDFF and MRS are seamlessly integrated into the complex structure of the overall trial
- Hands-on regulatory affairs to guide Sponsors through the fastest path to commercial success

Our Sponsors gain a competitive edge with our integrated full-service approach in the ever-evolving landscape of NAFLD/NASH drug clinical development. Our experience, coupled with our strong relationships with KOLs and investigative sites as well as our in-house central lab and imaging core lab services, set Sponsors up for long term success.



EXPERT INSIGHT

Our highly experienced medical, regulatory, and operational experts work collaboratively to execute clinical trials. We understand issues from the perspective of Sponsors, clinical investigators, scientific leaders, and the reviewers at regulatory agencies. With this insight, we can successfully define and execute clear development plans from beginning to end.

Medpace has the medical expertise, global experience, central labs, imaging labs and site relationships to complete successful studies for Sponsors.

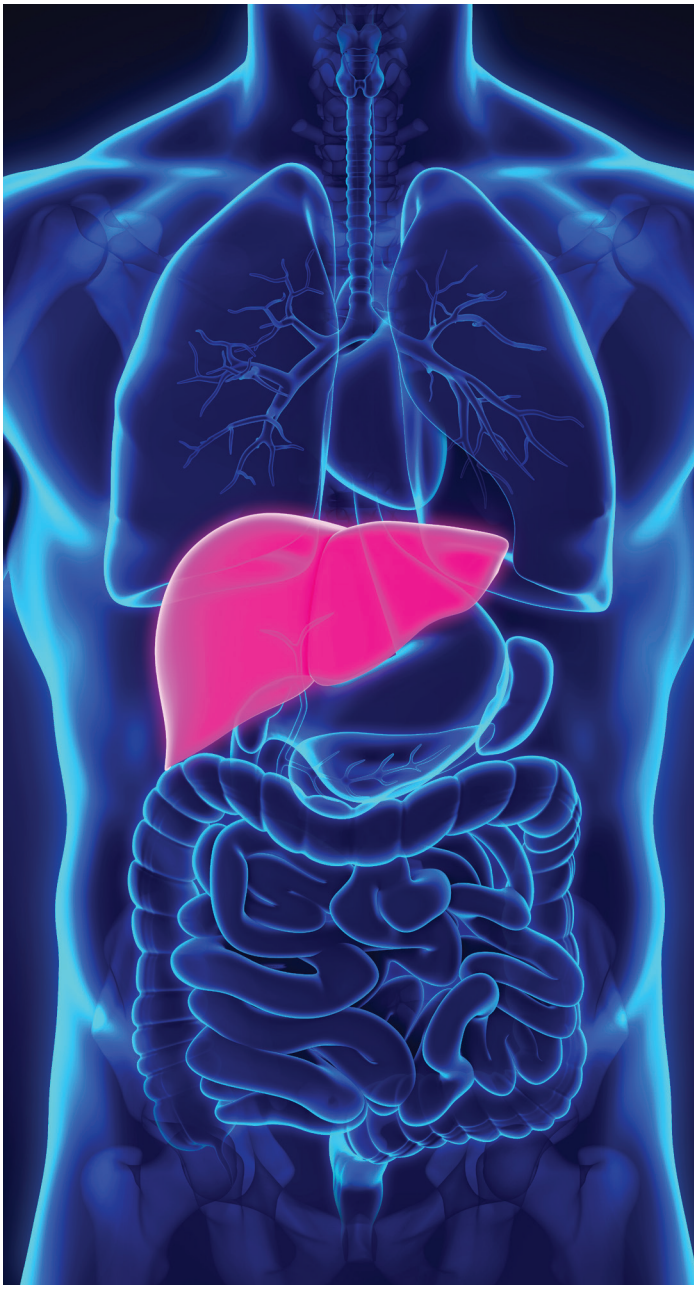
EXPERIENCE

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 ten 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.

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.



With our unique approach to clinical research, we have earned a reputation for taking on some of the most complex and challenging studies in the industry.

EXPERTS

SCIENTIFIC-DRIVEN DEVELOPMENT

Medpace is unique in its scientifically-driven approach to clinical research. The Medpace model gives Sponsors the advantage of early and ongoing insight and guidance from therapeutic experts throughout the 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. They are embedded throughout your studies, providing greater depth and the ability to tackle complex and challenging diseases.

In-House Physicians

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

Yulia Lurye, MD
Senior Medical Director, Medical Department

Phillippa Miranda, MD
Vice-President, Medical Department

Traci Turner, MD
Vice President, MRL Operations & MARC

ADVANCED CLINICAL PRACTITIONERS ADD A PATIENT'S PERSPECTIVE

Our medical directors are supported by a team of experienced ACPs whose unique perspective brings added value to the clinical development team. These highly trained experts with advanced degrees and hands-on clinical experience provide an additional layer of knowledge and insights that can streamline your studies and address potential challenges early in the study planning. ACPs are embedded in the teams to ensure your study is feasible and operationalized for efficient execution by looking at the protocol through the lens of the patient and site staff. ACPs also help with the review of safety events, ongoing team education, recruitment strategies, and study document review. Their understanding of what works in a clinical setting makes them a valuable part of our embedded medical expertise model.

Susan Brumm DNP, ANP-C, BC-ADM
Advanced Clinical Practitioner

Katherine Monday, MSN, APRN, NP-C
Advanced Clinical Practitioner

Piotr Krzeski, MD, PhD, FFPM

Senior Medical Director, Medical Department

Dr. Piotr Krzeski is an experienced internist with 20 years of experience in gastroenterology and hepatology, including NAFLD and NASH.

Experience Summary

- An internist with a broad background in pharmaceutical research
- 20 years' experience in clinical drug development
- Global expertise in the design and medical oversight of clinical trials in the area of gastroenterology and hepatology including NAFLD and NASH
- Recognized in the field for his contribution to the pioneering work on standardization of central imaging in drug development

Education Summary

- Diploma in Pharmaceutical Medicine, Royal Colleges of Physicians
- Doctor of Philosophy in Medical Sciences in Hepatology, Medical Centre for Postgraduate Education
- Medical Degree, Warsaw Medical Academy

Yulia Lurye, MD

Sr. Medical Director, Medical Department

Dr. Yulia Lurye is a clinical research physician with board-certifications in endocrinology and pediatric endocrinology and nephrology.

Experience Summary

- 10+ years of clinical trial experience, including three years as an investigator and eight as a medical director working across all phases within a Clinical Research Organization
- Therapeutic areas include metabolic disorders, cardiovascular, infectious diseases, kidney/renal and liver diseases, transplantation and immunosuppressive therapy, rare diseases, and growth disorders. Therapeutic modalities/products include small molecules, biologics and biosimilars, advanced gene and cell therapies, and medical devices
- 10+ years of clinical practice in diabetes and CKD, and years of clinical practice in the transplantation of solid organs (kidney, pancreas, liver, intestine, heart, lung) into adults and children
- Research work on predictive models of survival after solid organ transplantation, bone marrow stem cell therapy and IGF-1/growth hormone imbalances in children with liver cirrhosis

Education Summary

- Doctor of Medicine, Russian State Medical Academy (Honors)
- Residency in internal medicine
- Fellowship in endocrinology, pediatric endocrinology, and nephrology
- Holds certificates in endocrinology, pediatric endocrinology and nephrology, liver transplantation, kidney and pancreas transplantation

Phillippa Miranda, MD

Vice President, Medical Department

Dr. Miranda is board certified in Endocrinology, Diabetes, and Metabolism and has extensive experience in the conduct of Phase II and III studies in diabetes and endocrinology.

Experience Summary

- Served on the faculty in the Division of Endocrinology at Duke University Health System for five years before transitioning to industry
- Twelve years of experience in clinical drug development including the planning and execution of clinical research studies as the lead CRO medical monitor
- Therapeutic expertise covers a wide range of metabolic indications with significant medical monitoring experience in the areas of type 2 diabetes, type 1 diabetes, obesity, and NASH

Education Summary

- Doctor of Medicine, Duke University School of Medicine
- Residency in Internal Medicine, Duke University School of Medicine
- Fellowship in Diabetes and Endocrinology, Duke University School of Medicine

Traci Turner

Vice President, MRL Operations & MARC

Dr. Traci Turner is board certified in internal medicine and brings 15 years' experience in central laboratory operations in drug development.

Experience Summary

- Board-certified in Internal Medicine and is a Diplomate with the American Board of Clinical Lipidology
- Principal Investigator 50+ clinical trials with lipid modifying therapies, Phase 1 - 3 trials
- Overseen the successful completion of > 150 lipid trials, with multiple indications such as hypertriglyceridemia, dyslipidemia, non-FH and FH hypercholesterolemia, lipodystrophies, and FCS, including providing efficacy analyses for PCSK9 inhibitors that supported acceptance of FDA BLAs, European & Global filings, and subsequent approvals.
- Active member of the American Heart Association, National Lipid Association, and holds certification in Medical Technology from the American Society of Clinical Pathologists.

Education Summary

- Doctor of Medicine, University of Cincinnati – Cincinnati, OH
- Residency, Internal Medicine, University Hospital - Cincinnati, OH
- Bachelor of Science in Medical Technology, University of Cincinnati – Cincinnati, OH

Susan Brumm, DNP, ANP-C, BC-ADM

Advanced Clinical Practitioner

Ms. Brumm is a board-certified Advanced Clinical Practitioner and board-certified in Advanced Diabetes Management.

Experience Summary

- Saw patients discharged face-to-face weekly in a Diabetes Transition Clinic and modified plans of care to reduce HgA1c levels, readmissions, and transition patients back to primary care
- Provided patient and family diabetes self-management education
- Wrote and educated nurses on DKA (Diabetic Ketoacidosis) order set and the insulin drip protocol, and Acute Care Residents in orientation monthly on basal, bolus, correction order sets, policies, and insulin drip management policies
- Interrogated insulin pumps for inpatients and transitioned them to basal, bolus orders
- Principal Investigator (PI) on a Quality Improvement Project with primary care and telehealth to reduce readmissions and HgA1c levels
- Primary author and PI on a Quality Improvement project, decreasing 30-day readmissions and HgA1c published in The Diabetes Educator in 2016

Education Summary

- Doctorate in Nursing Practice, Xavier University
- Post-Master's Nurse Practitioner Certificate, Northern Kentucky University
- Master of Science in Nursing, Xavier University

Katherine Monday, MSN, APRN, NP-C

Advanced Clinical Practitioner

Ms. Monday is a board-certified Advanced Clinical Practitioner with over 10 years of experience in clinical practice.

Experience Summary

- Served as both Sub-Investigator and study coordinator for clinical trials, managing patient recruitment, patient study visits, and regulatory documentation
- 7 years' experience in internal medicine managing acute and chronic conditions, which a particular focus on education of patient and family
- Experience in gastroenterology specialty, managing acute and chronic gastrointestinal conditions
- Managed anticoagulation care for approximately 30+ patients
- Served as Inflammatory Bowel Disease Transition Coordinator, coordinating the transition of patients from pediatrics to adult care
- As a registered nurse, worked at Cincinnati Children's Hospital Medical Center caring for patients with liver and bowel conditions, including those undergoing liver/small bowel transplantation

Education Summary

- Bachelor of Science in Nursing, Purdue University – West Lafayette, IN
- Master of Science in Nursing, University of Cincinnati – Cincinnati, OH

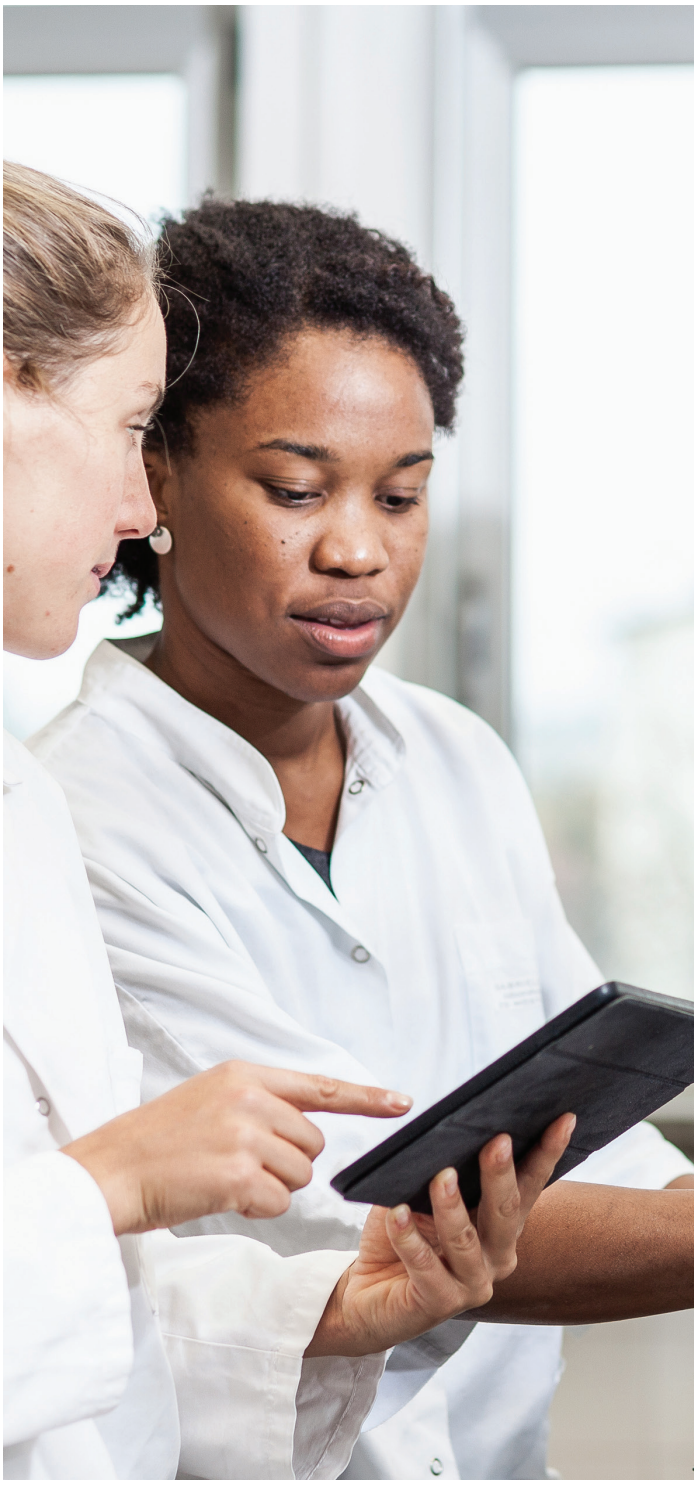
EXECUTION

DRIVING EFFICIENT AND CONSISTENT DATA FOR GLOBAL STUDIES

Achieve quality results, meet deadlines, and maximize efficiencies by partnering with a CRO that excels in execution. Medpace demonstrates a commitment to quality and a dedication to conducting full-service studies in an exacting manner to produce the highest quality results.

KEYS TO SUCCESSFUL EXECUTION

- **Committed Teams:** With turnover rates that are lower than the industry standard, our team is with you from project initiation to completion. As a result, we typically develop better team dynamics based on trust and respect
- **Resourcefulness:** Medpace promotes a culture of problem-solving. Our global operational staff proactively identify potential issues and communicate solutions, ensuring your sites and studies are managed effectively and efficiently
- **Site and KOL relationships:** Leveraging Medpace's long history in metabolic clinical trials as well as years in GI/hepatology space, we can select the best sites for your specific program. This provides an advantage in meeting your recruitment timelines with high quality data. Medpace has received multiple awards recognizing Medpace as a leading global CRO, particularly noting the excellence and training of our CRAs
- **Regulatory Support:** Medpace offers a dedicated global regulatory submissions team as well as global regulatory affairs for comprehensive support



EXECUTION

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 (MRI-PDFF; magnitude and complex) and Magnetic Resonance Elastography (MRE) to support imaging endpoints for NAFLD/NASH trials using fully regulatory-compliant platforms.

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization 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.