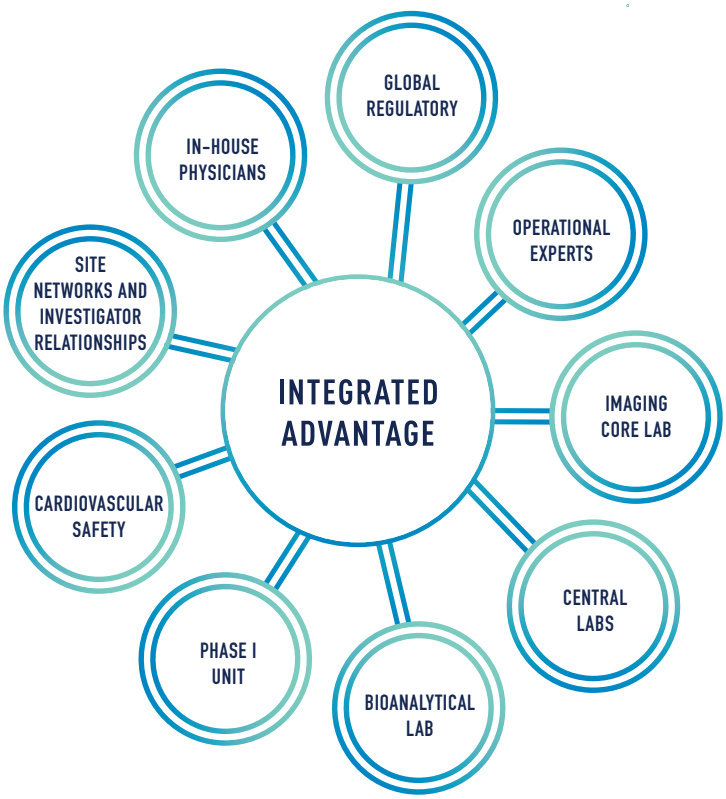
A DEEPER DIVE INTO ENDOCRINE AND METABOLIC CLINICAL DEVELOPMENT

AN INTEGRATED ADVANTAGE

For nearly 30 years, Medpace has specialized in the design and conduct of global trials for endocrine and metabolic diseases and disorders. We bring a global footprint, strategic medical, regulatory, and operational leadership, as well as fully integrated services including central labs, a bioanalytical lab, imaging core lab, ECG/cardiac safety, and a Phase I unit.

Key differentiators include:

- Highly experienced teams of medical, operational, and regulatory experts
- We've conducted hundreds of trials around the globe for drug, device, and combination products
- Our preferred provider relationships with key sites specialized in recruiting patients with endocrine and metabolic diseases expedites site start-up, enhances recruitment and maximizes trial efficiency
- An endless suite of global imaging services seamlessly integrate into the overall structure of clinical trials
- We offer a wide range of relevant biomarker assays through our wholly-owned central laboratories
- Our bioanalytical lab has experience in a broad range of small and large molecule bioanalytical and biomarker support
- Our cardiovascular core lab provides ECG acquisition and analysis services, allowing results to be interpreted in the context of all the other data
- A Phase I unit located on our corporate campus in Cincinnati, OH is dedicated to the conduct of early-phase clinical pharmacology studies in normal healthy volunteers, special populations, and patient populations



COLLABORATIVE & CROSS-FUNCTIONAL TEAMS

Medpace is unique in its scientifically-driven approach to clinical research. Our model gives Sponsors the advantage of early and ongoing insight and guidance from a team of medical, regulatory, and operations experts throughout trial design and execution. We understand issues from the perspective of Sponsors, clinical investigators, scientific leaders, and reviewers at regulatory agencies. With this insight, we successfully define and execute clear development plans from beginning to end.

Medpace has conducted hundreds of endocrine and metabolic studies around the globe.

EXPERTS

Serving as therapeutic team leaders, our in-house medical doctors provide strategic direction for study design and planning. They train operational staff, work with Investigators, provide medical monitoring, and meet with regulatory agencies as well as our global regulatory affairs experts to provide strategic guidance into the best pathways to accelerate approvals. Our MDs are embedded throughout every study, providing greater depth of expertise and the ability to tackle complex and challenging diseases.

In-House Physicians

Ruchi Bhabhra, MD, PhD
Medical Director

Nancy Campbell, MD
Senior Medical Director

Terence Eagleton, MB, BS (Hons)
Senior Medical Director

Piotr Krzeski, MD, PhD, FFPM
Vice President

Douglas Lee, MB, BCh, MRCP, MBA
Senior Medical Director

Yulia Lurye, MD
Senior Medical Director

Phillippa Miranda, MD
Vice-President

Traci Turner, MD
Vice President, MRL Operations & MARC

Ivana Zib, MD
Senior Medical Director

ADVANCED CLINICAL PRACTITIONERS ADD A PATIENT'S PERSPECTIVE

Our medical directors are supported by 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

Ruchi Bhabhra, MD, PhD

Medical Director, Medical Department

Dr. Ruchi Bhabhra is board-certified in Endocrinology with over 10 years of experience in academia and clinical practice in addition to extensive research experience.

Experience Summary

- Basic science research during PhD, translational research during fellowship and served as a PI for clinical trials during her faculty appointment
- 10 + years of experience providing patient care in an academic setting with therapeutic expertise in diabetes, hyperlipidemia, thyroid disorders, pituitary and adrenal diseases, hypogonadism, PCOS, calcium and bone disorders
- Established a neuroendocrine clinic in collaboration with Neurosurgery to focus on pituitary diseases
- Educator and mentor for Internal Medicine Residents and Endocrinology Fellows
- Multiple invited lectures and publications in peer reviewed journals
- Member of The Endocrine Society and The Pituitary Society

Education Summary

- Bachelor of Medicine and Bachelor of Surgery, Jawaharlal Nehru Medical College – Ajmer, India
- Doctor of Philosophy in Pathobiology and Molecular Medicine, University of Cincinnati – Cincinnati
- Residency in Internal Medicine, The Christ hospital – Cincinnati
- Endocrinology Fellowship, University of Virginia – Charlottesville

Nancy Campbell, MD

Senior Medical Director, Medical Department

Dr. Nancy Campbell is board certified in Family Medicine with over 25 years of experience in clinical practice, academia, and clinical research. She is experienced as a medical monitor in rare disease, CNS, psychiatry, metabolic, GI, and respiratory in both pediatrics and adults in Phase I-IV trials.

Experience Summary

- Served as a Clinical Assistant Professor of Family Medicine for ten years
- Worked in clinical research for 15 years
- Was the Executive Medical Director at a global CRO for five years
- Worked as Medical Director of two clinical research centers
- Participated as the Principal Investigator on more than 140 multi-specialty clinical trials in Phase I-IV in both adults and pediatrics in the therapeutic areas of allergy/immunology, CNS, metabolic, respiratory, urology, vaccines, cardiovascular, and women's health
- Spent ten years as a Registered Nurse in post-op cardiovascular and medical/surgical before her career as a physician

Education Summary

- Doctor of Medicine, Baylor College of Medicine
- Residency in Family Medicine, University of Texas Health Science Center
- Bachelor of Science in Nursing, University of Texas Medical Branch in Galveston

Terence Eagleton, MB, BS, (Hons)

Senior Medical Director, Medical Department

Director Dr. Terence Eagleton is an experienced physician with years of experience with rare disease, respiratory, and infectious diseases.

Experience Summary

- Extensive experience in rare and ultra-rare diseases
- Numerous manuscripts published in international peer-reviewed medical and scientific journals
- General surgical training (with a significant neurosurgical component) and experience with a wide variety of therapeutic areas and clinical phases

Education Summary

- Bachelor of Medicine and Bachelor of Surgery (Honors), University of London
- Bachelor of Science in Physiology (Honors), University of London

Piotr Krzeski, MD, PhD, FFPM

Vice President, 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

Douglas Lee MB BCh, MRCP, MBA

Senior Medical Director, Medical Department

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.

Experience Summary

- Currently a clinical reviewer for the journal Diabetes, Obesity and Metabolism
- Before 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 three Endocrinology and Metabolic products, under the European Centralized Procedure

Education Summary

- Dr. Lee received his Bachelor of Medicine, Bachelor of Surgery at the Queen's University Medical School in the United Kingdom (UK)
- Achieved his Membership of the Royal College of Physicians in the UK
- Earned his MBA from the Imperial College of London in 2013

Yulia Lurye, MD

Senior 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, MD

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 I - III trials
- Has overseen the 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
- An active member of the American Heart Association, National Lipid Association, and holds a certification in Medical Technology from the American Society of Clinical Pathologists

Education Summary

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

Ivana Zib, MD

Sr. Medical Director

Dr. Ivana Zib is board certified in Internal Medicine and Diabetes, Endocrinology and metabolic disease and has more than 15 years of experience working in clinical research.

Experience Summary

- 8 years' experience in pharmaceutic industry/ clinical trials
- 10 years' experience working in clinical research as a Principal or Co-investigator
- 14 years' experience in patient care in Internal Medicine, Diabetes, Endocrinology and metabolic diseases
- Teaching and research experience in University Hospitals in Endocrinology, Diabetes and Metabolism
- Therapeutic Areas expertise in woman health, diabetes and metabolism, endocrinology and rare disease

Education Summary

- Doctor of Medicine, Charles University - Czech Republic
- Residency in Internal Medicine, University of Pittsburgh Medical Center – Pittsburgh Pennsylvania
- Fellowship in Endocrinology, University of Texas Southwestern Medical Center – Dallas Texas

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

EXPERIENCE

MANAGEMENT OF HUNDREDS OF TRIALS GLOBALLY, ACROSS ALL PHASES

Medpace's experience in clinical development for endocrine and metabolic diseases is extensive. We have designed and executed full clinical development plans from trial start-up to NDAs and marketing submissions.

Metabolic/Endocrine Experience by Compound:

- PCSK9 inhibitors
- SGLT-2 inhibitors
- Insulins: concentrated, inhaled, rapid-acting, long-acting
- GLP-1 agonists
- Diabetes management apps
- Appetite suppressants
- Kisspeptin modulators
- Omega-3s
- Anti-sense oligonucleotides
- Glucagon antagonists
- Amylin analogs
- Autologous stem cell therapies
- Gene therapies
- Glucometers
- Low-calorie sweeteners
- GIP receptor agonists
- Grhelin agonists
- Osteogenesis modulators
- DPPIV inhibitors
- Novel glucagons
- Novel octreotides
- Novel testosterones
- Novel growth hormones
- Thyroid receptor agonists
- Glycation assays
- Cholesterol absorption inhibitors
- ACE inhibitors
- TZDs
- Fibrates
- Statins
- Biguanides

Example Patient Populations:

- Diet-controlled and treatment naïve patients
- Metformin-only treated patients
- Patients with narrow HbA1c inclusion ranges
- Patients with uncontrolled diabetes on routine background therapies
- Elderly patients
- Patients with diabetes and hypercholesterolemia or mixed dyslipidemia
- Patients with disease-related renal or neurologic impairment, diabetic cardiomyopathy, or gastorintestinal complications including gastroparesis
- Patients on continuous glucose monitoring

EXECUTION

Medpace offers a distinct advantage to Sponsors developing therapeutics for endocrine and metabolic diseases. We have the in-house experts, extensive experience, as well as a unique model for execution that includes the integration of critical services such as labs, imaging and safety.

KEYS TO SUCCESSFUL EXECUTION

Cross-functional teams: Our in-house medical, regulatory, and operational teams work as a collaborative unit. This team is supported by other experts in related therapeutic and specialty areas as well as experts from our labs, and imaging and ECG core labs.

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.

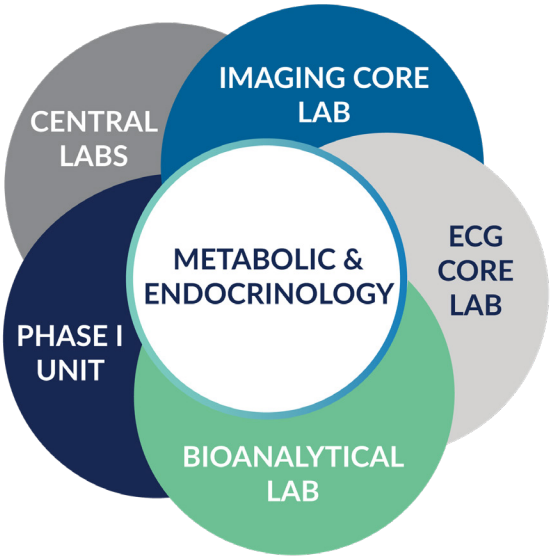
Site and KOL relationships: With our depth of experience and proven relationships with Investigators and Key Opinion Leaders worldwide, we can select the best sites for your specific program. This provides an advantage in meeting your recruitment timelines with high quality data.

Exceptional training: We have 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.

INTEGRATED SERVICES

Medpace offers comprehensive and fully-integrated services including global central labs, 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 trials of all sizes and scope.



Central Lab: PD analysis, biomarker assay development and validation

Medpace's central laboratories have unparalleled experience and expertise in the development of diabetes, lipid and cardiovascular modifying therapies. Key staff involves doctors, managers, and technologists with considerable expertise in the area of central laboratory operations for the pharmaceutical industry and federally funded programs, from discovery and proof of concept through large, long term global trials.

- Four global, harmonized, Medpace owned, purpose built central lab locations: US, Belgium, Singapore, China
- Extensive test menu of validated biomarkers
- A global team of hands-on laboratory PhDs who actively engage with your study team to identify and validate additional biomarkers to support your study program
- Experienced and stable project management team

Bioanalytical Laboratory: PK Analysis

- Leveraging state-of-the-art instrumentation, techniques, and facilities, our team of experts has experience in a broad range of small and large molecule bioanalytical and biomarker support
- Working in a good laboratory practice (GLP) compliant setting, the Medpace Bioanalytical Laboratories provide method development, transfer, validation, and analysis of preclinical and clinical biological samples
- We have extensive expertise in developing sensitive methods for LC-MS/MS — qualifying multiple-analytes, metabolites, prodrugs, and light- and temperature-sensitive compounds
- Our discovery team regularly supports fast PK, bioavailability, and early toxicology studies

Imaging Core Lab

- Board-certified radiologists and endocrinologists demonstrating extensive clinical trial experience with complex CT, MR and DXA assessments
- In-house, registered CT, MR and DXA technologists who maintain a widespread knowledge in qualifying sites with customized and advanced data and acquisition protocols
- Integrated team of technologists, physicians, and medical physicists collectively possessing years of experience with imaging studies, that utilize the CT, MRI and DXA modalities, and their respective analysis and quality control checks
- Imaging project managers that specialize in managing imaging trials utilizing these modalities, designing and testing novel phantoms specifically for hepatic fat fraction assessment in MR Imaging

ECG Core Lab

Given the importance of accessing cardiovascular risk and cardiovascular monitoring in many endocrine and metabolic trials, Medpace's ECG core lab provides yet another layer of integrated efficiency.

- Provides ECG acquisition and analysis services utilizing industry standard devices and systems, allowing ECG results to be interpreted in the context of all the other data Medpace
- In-house physicians and cardiology with excellent peer to peer relationships with KOLs
- Extensive global experience with trial design, data interpretation and analysis, global study management, and regulatory strategy consultation

Phase I Unit

Medpace's Clinical Pharmacology Unit (CPU) is dedicated to the conduct of early-phase clinical pharmacology studies in normal healthy volunteers, special populations, and patient populations. The Phase I Unit is located on the Medpace clinical research campus, centrally located in Cincinnati, Ohio.

Supporting a wide spectrum of study capabilities:

- Dose escalation
- Single/multiple dose including QTc waiver component
- First-in-human (FIH)
- Bioavailability / Bioequivalence
- Drug-Drug interaction
- Food effect
- Phase IIa / Proof of concept
- Thorough QT / QTc
- Device and diagnostics
- Dose forms (e.g. IV/Sub-q, oral, nasal, topical

CLINTRAK® STUDY MANAGEMENT TECHNOLOGY

ClinTrak (centralized CTMS) provides access to comprehensive study details in a single sign-on, facilitating team coordination and decision support for sponsors and sites.

Lab: The ClinTrak Lab component is a full-scale Laboratory Information Management System (LIMS) that provides access to daily lab reports, management information, cumulative results and trend graphing, secure role-based access, and study specific project management pages.

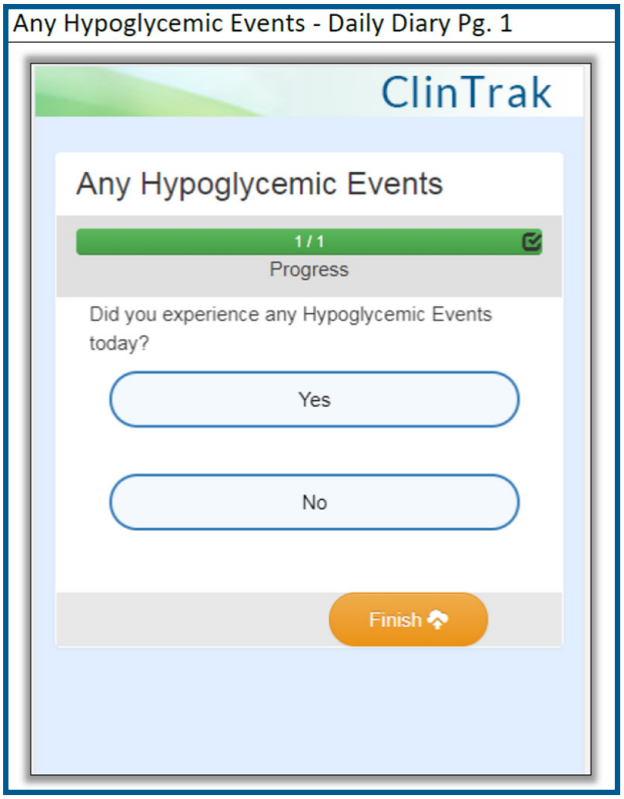
Imaging: The ClinTrak Imaging component integrates image tracking, quantitative and qualitative analysis, and data management to store and manage data from all imaging and reading centers.

Patient Reported Outcomes (ePRO/eDiary): Patients are more likely to be engaged in clinical trials when the process is transparent and they can understand their role in the research that may lead to advancements in the treatment or diagnosis of their conditions. Our TrialPACE™ app allows for the safe and secure collection of PRO data directly from patients through multiple platforms.

Sites: Our OnPace™ site app was developed to assist sites in preparing for each study visit by providing a clear overview of all assessments, access to study documentation such as the protocol and IB and links to all study websites.

PATIENT RECRUITMENT AND RETENTION PLATFORM

IntelliPACE® is Medpace's in-house program for successful and expedited patient recruitment. Driven by external and internal data sources (including our proprietary study management system, ClinTrak®), we leverage our well-profiled network of sites and relationships with PIs and KOLs to determine feasibility and to develop a well-vetted recruitment strategy. Once identified, our specialized recruitment teams ensure well-coordinated and efficient execution.



TrialPACE is an intuitive app that can increase subject participation.

FULL-SERVICE CLINICAL DEVELOPMENT

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.

MAKING THE COMPLEX SEAMLESS™