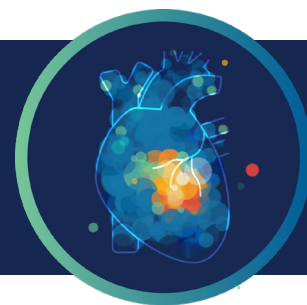


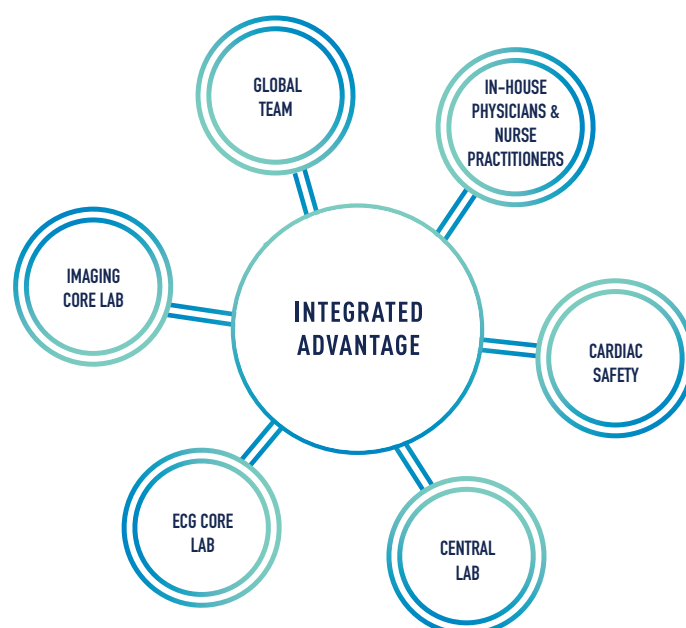
A DEEPER DIVE INTO CARDIOVASCULAR CLINICAL DEVELOPMENT



AN INTEGRATED ADVANTAGE

As a full-service and therapeutically-focused CRO, Medpace specializes in the design and conduct of global trials in cardiovascular clinical research. We bring a global footprint, strategic medical, regulatory and operational leadership as well as fully integrated Central Labs and Core Imaging services to accelerate cardiovascular studies.

- Global long-term relationships with experienced sites, key opinion leaders, advocacy groups, and academic research organizations
- Integrated imaging and central lab services ensuring seamless logistics, review and testing
- Cardiovascular medical experts who provide strategic, educational and practical leadership
- Experienced Trial Managers to drive efficiency and quality cardiovascular training program for all operational staff
- Best positioned to partner with small to mid-sized biotech



Medpace is a recognized leader in managing Cardiovascular drug/device clinical trials.

THERAPEUTICALLY-FOCUSED TEAM

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 therapeutic experts throughout trial design and execution. Our highly-experienced team of medical, regulatory, and operational experts work collaboratively to conduct clinical trials. 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.



EXPERTS

Serving as therapeutic team leaders, our in-house medical doctors provide strategic direction for study design and planning, 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.



Nicholas Alp, MD,
PhD, FACC, FRCP
Sr. Vice President,
Medical Department



Theo Hoofwijk, MD
Vice President,
Medical Department



Dean Kereiakes,
MD, FACC, FSCAI
Vice President,
Medical Department



Dr. Richard Lee, MD
Vice President,
Medical Department



Marco Tangelder,
MD, PhD
Sr. Medical Director



Adam Lubert, MD
Medical Director



Aung Myat, MD
Medical Director

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.



Sarah Casey,
MSN, APRN, AGACNP
Advanced Clinical
Practitioner



Fredrica Francia,
MSc, RN
Advanced Clinical
Practitioner



Audrey Hau,
MSc, RGN
Advanced Clinical
Practitioner



Sharlene Hogan,
MSc Cardiology, RGN
Advanced Clinical
Practitioner



Brandon Kinworthy,
MSN, APRN,
AGACNP-BC
Advanced Clinical
Practitioner



Tracey Vitori, PhD,
MS, APRN, ACNP-BC
Advanced Clinical
Practitioner



Nicholas Alp, MD, PhD, FACC, FRCP

Sr. Vice President, Medical Department

Dr. Nicholas Alp is a board-certified academic cardiologist and clinician scientist. He brings 25+ years of experience in drug and medical device development, focused on cardiovascular, metabolic, and rare diseases.

Experience Summary

- Held multiple VP roles at Clinical Research Organizations
- Active member in multiple professional cardiovascular societies
- Key opinion leader with over 70 publications and books
- Experience in Clinical Research for 25+ years

Education Summary

- Doctor of Medicine, Oxford University – Oxford, UK
- Bachelor of Medicine, Oxford University – Oxford, UK
- Doctor of Philosophy, Cambridge University – Cambridge, UK
- Bachelor of Science, London University – London, UK



Theo Hoofwijk, MD

Vice President, Medical Department

Dr. Theo Hoofwijk is a graduate of the University of Amsterdam, from which he received his Medical Degree. He brings more than 25 years of experience working within CROs and the pharmaceutical industry to the Medpace team.

Experience Summary

- Extensive experience in drug safety, clinical drug development, and medical affairs research in both local country operations and corporate pharma environment
- Held executive and director roles in international pharmaceutical companies and CROs
- Led strategic drug development activities for pharma customers
- Managed global programs in the gastroenterology and cardiovascular therapeutic areas
- Developed, lead, and supported clinical development programs in functional bowel diseases, orthotopic liver transplantation, inflammatory bowel disease, dyslipidemia, acute coronary syndromes, coronary artery disease, heart failure, essential hypertension, and type 2 diabetes mellitus
- Member of Dutch Association of Clinical Pharmacology and Biopharmacy Netherlands
- Member of Dutch Association of Pharmaceutical Physicians

Education Summary

- Doctor of Medicine, University of Amsterdam, the Netherlands
- Residency in Surgery, De Heel Hospital, Zaandam, the Netherlands
- Residency in Internal Medicine, de Heel Hospital, Zaandam the Netherlands



Dean Kereiakes, MD, FACC, FSCAI

Vice President, Medical Department

Dr. Dean Kereiakes is a board certified Cardiologist. He brings 38+ years of experience in Clinical Research, Academia, and Clinical Practice.

Experience Summary

- Holds multiple Director roles at Clinical Research Organizations and Hospitals
- Active member in multiple professional societies in Cardiology
- Fellow of the American College of Cardiology and Society for Cardiovascular Angiography and Interventions
- Key opinion leader with over 900 scientific peer reviewed abstract and manuscript publications, 15 book chapters and monographs, 400+ Lectures
- Experience in Clinical Research, Clinical trial design and development for 33+ years

Education Summary

- Bachelor of Science in Biology, University of Cincinnati – Cincinnati, OH
- Doctor of Medicine, University of Cincinnati – Cincinnati, OH
- Medical Resident, University of California – San Francisco, CA
- Senior Medical Resident, Massachusetts General Hospital, Boston, MA
- Chief Medical Resident, University of California – San Francisco, CA
- Fellow, Adult Cardiology, University of California – San Francisco, CA
- Fellow, Coronary Angioplasty, San Francisco Heart Institute, Seton Medical Center – Daly City, CA
- Fellow, Coronary Angioplasty, Sequoia Hospital – Redwood City, CA
- Honorary Doctor of Science, University of Cincinnati – Cincinnati, OH

Richard Lee, MD

Vice President, Medical Department

Dr. Lee is a board-certified cardiothoracic surgeon. He brings over 20 years of experience in Pre-Clinical Research, Academia, and Clinical Practice.

Experience Summary

- American Board of Thoracic Surgery certification
- Active member of Society of Thoracic Surgeons
- Extensive background in a full range of adult cardiothoracic surgery and cardiovascular devices
- Held department leadership roles in academic and non-academic clinical practice
- Developed guidelines and protocols for bloodless medicine and surgery program
- Served on hospital ethics committee

Education Summary

- Doctor of Medicine, Cum Laude, Harvard Medical School – Boston, MA
- Bachelor of Science in Molecular Biophysics and Biochemistry, Summa Cum Laude, Yale University
- Research Fellow, Renal Unit & Transplantation Unit, Harvard Medical School, Massachusetts General Hospital – Boston, MA
- Surgical Research Fellow, Transplantation Biology, Massachusetts General Hospital – Boston, MA
- Resident, General Surgery, Massachusetts General Hospital – Boston, MA
- Fellow, Cardiothoracic Surgery, Stanford University Medical Center – Stanford, CA



Marco Tangelder, MD, PhD

Sr. Medical Director

Dr. Marco Tangelder is a board-certified Clinical Epidemiologist. He brings 30+ years of experience in Clinical Research and Drug Development.

Experience Summary

- Held multiple academic and Sr. Director roles at Drug Development Companies
- Research areas include vascular surgery, vascular medicine, thrombosis and hemostasis, peripheral arterial disease, coronary artery disease, atrial fibrillation
- Active member in multiple professional affiliations revolving around Cardiology
- Board Member of the International Surgical Thrombosis Forum (ISTF)
- Key opinion leader with over 50 scientific publications

Education Summary

- Doctor of Medicine, University of Utrecht — Utrecht, Netherlands
- Doctor of Philosophy, University of Utrecht — Utrecht, Netherlands
- Residency in Surgery, Twenteborg Hospital Almelo — Almelo, Netherlands
- Fellowship, Vascular Surgery, University Medical Center Utrecht — Utrecht Netherlands
- Master of Science in Epidemiology, University of Utrecht — Utrecht, Netherlands
- Master in Pharmaceutical Medicine, Medical University Karolinska Institutet — Stockholm, Sweden

Adam Lubert, MD

Medical Director

Dr. Adam Lubert is a pediatric and adult congenital cardiologist with over 10 years of experience in clinical practice, academia, and clinical research.

Experience Summary

- Board-certified in internal medicine, pediatrics, pediatric cardiology, and adult congenital heart disease
- Served as a pediatric and adult congenital cardiologist on faculty at Cincinnati Children's Hospital
- Directed the Fontan Management Program and led a multidisciplinary team of healthcare providers to optimize the care of children and adults who underwent the Fontan procedure
- Key opinion leader, authoring over 40 peer-reviewed articles in the fields of pediatric and adult congenital cardiology

Education Summary

- Doctor of Medicine, Wayne State University – Detroit, MI
- Bachelor of Science in Chemistry, University of Michigan – Ann Arbor, MI



Aung Myat, MD

Medical Director

Dr. Aung Myat is a board-certified interventional cardiologist and clinician scientist. He brings more than 20 years of professional medical experience and an established track record in clinical research, academia, and medical education.

Experience Summary

- Leader of a multidisciplinary healthcare professional team delivering protocol-driven treatment in an NHS Hospital Foundation Trust rated excellent by the Care Quality Commission
- Over 80 publications including original research, observational studies, state-of-the-art reviews, journal supplements, online educational material, textbooks and chapters
- Associate Editor at Heart (BMJ Journals)
- Course Director and Education Committee Member at the British Cardiovascular Society
- Research and Development Committee Member at the British Cardiovascular Intervention Society
- Member of the National Institute for Health Research Reviewer Development Scheme
- Regular manuscript reviewer for The Lancet, the British Medical Journal, and the European Heart Journal family of journals
- Lead Editor for the Challenging Concepts series of Medical and Surgical Textbooks published by Oxford University Press
- Lead Editor for the Interventional Cardiology Training Manual published by SpringerNature, Lead Editor for Challenging Concepts in Cardiovascular Medicine and Landmark Papers in Cardiovascular Medicine

Education Summary

- National Institute for Health Research Academic Clinical Lectureship, Brighton and Sussex Medical School
- British Heart Foundation Clinical Research Training Fellowship, King's College London
- Doctor of Medicine (Research), King's College London Membership of the Royal College of Physicians, London
- Bachelor of Medicine, Bachelor of Surgery (MBBS), King's College London
- Bachelor of Science in Biochemistry, United Medical and Dental Schools of Guy's and St Thomas', London

Sarah Casey, MSN, APRN, AGACNP

Advanced Clinical Practitioner

Ms. Casey is a board-certified Acute Care Adult Nurse Practitioner with over 10 years of cardiology experience in clinical practice and clinical research.

Experience Summary

- Experience assessing, diagnosing, and managing a variety of acute and complex cardiac medical conditions as an integral member of the advanced heart failure team in the cardiac intensive care unit at a large, private teaching hospital
- Extensive experience in managing mechanical circulatory systems
- Experience inserting and managing invasive lines, including arterial lines, central venous catheters, and Swan-Ganz catheters
- Active member in national cardiology and nurse practitioner organizations

Education Summary

- Master of Science in Nursing, University of Cincinnati
- Bachelor of Science in Nursing, Northern Kentucky University
- Adult-Gerontology Acute Care Nurse Practitioner (AGACNP), ANCC
- Registered Nurse, Kentucky



Fredrica Francia, MSc, RN

Advanced Clinical Practitioner

Ms. Francia is a board-certified Nurse Practitioner with 10 years of cardiology experience in clinical research and clinical practice.

Experience Summary

- Provided care for patients experiencing post-myocardial infarction, pre- and post-cardiac interventions, congestive heart failure, pulmonary hypertension, arrhythmias, endocarditis and vascular diseases
- Extensive experience in the set-up, management, and coordination of Phase I to IV clinical trials of medical devices and investigational products, ATMP trials, observational studies, and large real-world registries.
- Provided ongoing education and support to patients and their relatives regarding clinical trials and specific trial treatments
- Experience in the set-up and coordination of Patient and Public Involvement meetings
- Active member of the Royal College of Nursing (RCN)

Education Summary

- Master of Science in Evidence-Based Healthcare, University College London – London, UK
- Bachelor of Science in Nursing, Marche Polytechnic University – Ancona, Italy
- Registered Nurse (RN), Nursing and Midwifery Council, UK

Audrey Hau, MSc, RGN

Advanced Clinical Practitioner

Ms. Hau is a specialist nurse in cardiovascular research and intensive care medicine. She brings over 10 years of experience in Clinical Research and Clinical Practice.

Experience Summary

- Extensive experience in the acute care setting managing a full spectrum of cardiovascular indications in adults
- Extensive experience in the recruitment and follow-up of trial participants at site
- Extensive experience coordinating trials of medical devices and investigational medicinal products
- Guest speaker at multiple investigator meetings for high recruitment and retention performance
- Held leadership roles within clinical practice
- Active member of the Royal College of Nursing

Education Summary

- Bachelor of Science in Adult Nursing, Kingston University, United Kingdom
- Master of Science in Clinical Trials, University College London, United Kingdom
- Intensive Care Nursing Certification
- High Dependency Nursing Certification



Sharlene Hogan, MSc Cardiology, RGN

Advanced Clinical Practitioner

Mrs. Hogan is a registered nurse with the United Kingdom Nursing & Midwifery Council. She brings over 23 years of nursing experience.

Experience Summary

- Proficient clinical expertise in the acute setting managing adults with elective and emergency cardiac event: acute coronary syndrome, heart failure, arrhythmias and post procedure complications
- Extensive expertise as a catheter lab nurse assisting with invasive procedures and post procedural care such as the PAMI service (primary angioplasty for myocardial infarction), pulmonary vein isolation ablation, cardioversions, cardiac defibrillator and pacemaker insertion
- Expertise as a specialist nurse working autonomously by providing outpatient and community clinics in pre-assessment, patient information and advice, non-medical prescribing, medication management and lifestyle changes
- Leadership expertise in developing nurse-led cardioversion service ensuring informed consent, performing the external cardioversion, post procedure management and co-ordinating all aspects of service
- Integral educational role providing both formal and informal teaching for patients and staff. Developed a successful patient support group affiliated with national patient group Arrhythmia Alliance
- Research experience in invasive cardiology global and local trials recruiting, collecting and presenting research data

Education Summary

- Masters of Science-Cardiology 2012
- Diploma in Nursing 2000
- Registered General Nurse 1994
- Non Medical Prescribing 2015

Brandon Kinworthy, MSN, APRN, AGACNP-BC

Advanced Clinical Practitioner

Mr. Kinworthy is a board-certified Acute Care Adult Nurse Practitioner with over five years of cardiology experience at a large academic hospital.

Experience Summary

- Experience managing adult patients across the spectrum of cardiovascular diseases at Ohio State University hospital
- Provided cardiovascular expertise throughout the hospital setting
- Provided training and development for new nurse practitioners
- Provided daily education to patients and their families on disease process, appropriate management, and medication use
- Active member in national cardiology and nurse practitioner organizations

Education Summary

- Master of Science in Nursing, Ohio State University
- Adult Geriatric Acute Care Nurse Practitioner, ANCC
- Bachelor of Science, Ohio University
- Registered Nurse, Ohio



Tracey Vitori, PhD, MS, APRN, ACNP-BC

Advanced Clinical Practitioner

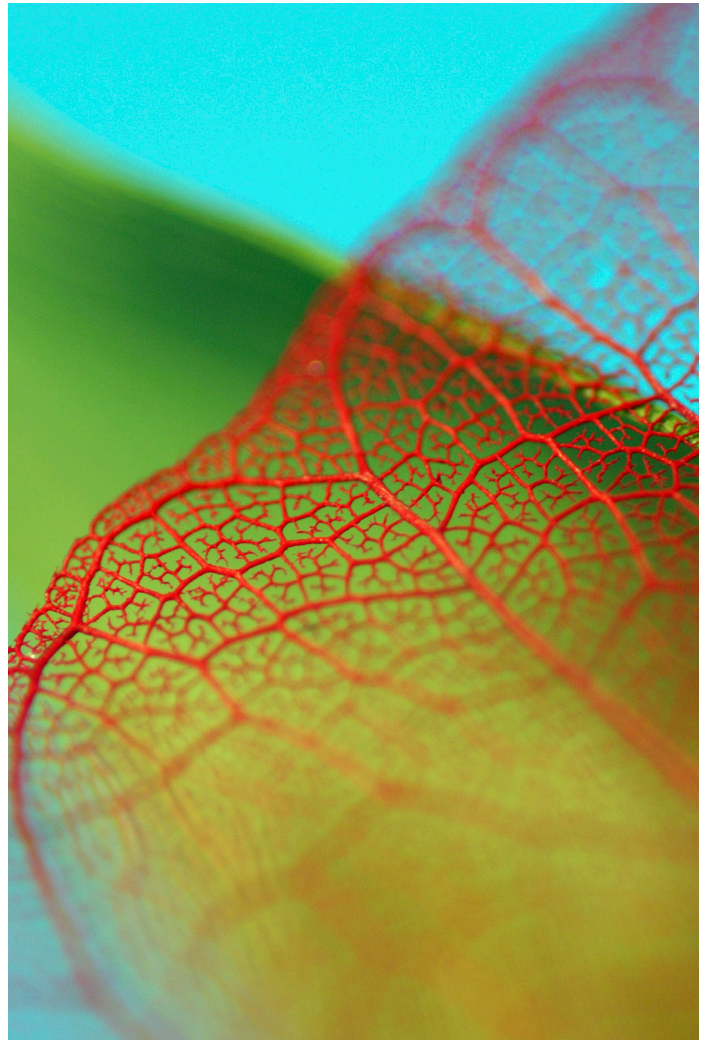
Dr. Tracey Vitori is a board-certified acute care nurse practitioner and clinical scientist. She brings over 30 years of Clinical Research, Academia, and Clinical Practice.

Experience Summary

- Extensive experience as Lead Advanced Practice Provider in cardiothoracic and vascular surgery, cardiovascular devices, and critical care in gerontological, adult, and neonatal settings
- Butler Williams Scholar with the National Institute of Health/National Institute of Aging.
- Molecular Biology Scholar with Boston College and New England Biolabs
- Developed and led biobehavioral, biospecimen, patient outcomes, humanoid robot, and pre-clinical research
- Leadership in proposal development, funding sourcing, trial management, and result dissemination
- Key opinion leader with multiple publications, abstracts, presentations, academic lectures, and is a peer reviewer for multiple professional research journals
- Content expert for Nurse Practitioner Examinations, ANCC
- Active member in multiple cardiovascular, gerontological, and nursing professional societies
- Leadership in Institutional Review Boards, Ethics Committees, and American College of Cardiology
- Instructional design expertise in developing protocols and training modules for patients, families, and clinicians

Education Summary

- Doctor of Philosophy, University of Kentucky
- Master of Science, Wright State University
- Master of Science in Nursing, University of Cincinnati
- Master of Education, Xavier University
- Bachelor of Science, College of Mount St. Joseph
- Registered Nurse, OH
- Acute Care Nurse Practitioner, ANCC



EXPERIENCE

The Medpace cardiovascular team has extensive global experience managing Phase I-IV programs in nearly every cardiac specialty. Medpace can effectively plan and conduct cardiovascular, drug/device combination and cardiac safety studies, especially large cardiovascular endpoint trials that demand rigorous safety requirements.

Medpace has Experience in the Following Therapeutic Categories:

- Acute coronary syndrome
- Hypertension
- Stroke
- Heart Failure
- Atherosclerosis
- STEMI and non-STEMI

Within Medpace, there is a group of operations professionals specifically dedicated to the design and conduct of medical device trials.

Our Cardiovascular Device Experience Spans:

- Valvular Disease
 - Aortic valve replacement (Percutaneous and surgical)
 - Mitral valve repair and replacement (Percutaneous and surgical)
- Coronary Artery Disease (interventional)
- Heart Failure
 - Ventricular assist devices
 - Chronic resynchronization therapy
 - Autonomic stimulation
- Electrophysiology
 - Pacemakers/Implantable cardioverter defibrillators
 - Ablation catheters
 - Mapping systems
- Cardiac Surgery
 - Coronary bypass grafts
 - Vessel occluders
- Congenital Heart Disease
- Endovascular/Interventional
 - Peripheral vascular disease
 - Carotid artery disease
 - Thrombectomy/Embolic protection
 - Aortic aneurysm



EXECUTION

DRIVING EFFICIENCIES AND CONSISTENCY OF DATA FOR GLOBAL STUDIES

Exceed your expectations by partnering with a CRO that delivers high-quality results, meets deadlines, and maximizes efficiencies. Operating under a full-service model, Medpace provides a therapeutically focused, integrated, global approach for seamless execution and quality results.

KEYS TO SUCCESSFUL EXECUTION

- **Committed Teams:** Your studies are assigned the best team from the onset and, with turnover rates that are lower than the industry standard, that team is with you from project initiation to completion. As a result, we typically develop better team dynamics that are 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:** Through our experience and relationships with Investigators and key opinion leaders (KOLs) worldwide, we can select the best sites for your specific study or program. This provides an advantage in meeting your recruitment timelines with high quality data. Medpace has received multiple awards from sites 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.

MEDPACE'S CARDIOVASCULAR PRECISION MEDICINE PROGRAM (CVPMP)

Medpace's Cardiovascular Division recognizes the importance of the emerging role of precision medicine in the field of cardiovascular disease whereby investigational drugs and therapies are focused on a subphenotype of patients with disease and/or a molecular target, e.g., gene, transcript, or peptide, that is associated with a disease. Medpace's in-house Cardiovascular Precision Medicine Program (CVPMP) — an extension of the Cardiovascular therapeutic team — is comprised of experts with extensive knowledge in the field of cardiovascular disease and precision medicine who aim to create a highly specialized partnership with industry sponsors seeking to develop therapies focused on disease subphenotypes and employ a patient-tailored approach.

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.

**WE CAN'T SIMPLIFY
CLINICAL DEVELOPMENT –
BUT WE CAN EXECUTE
IT SEAMLESSLY.**

MAKING THE COMPLEX
SEAMLESS®

