



# CARDIOVASCULAR

**Experts. Experience. Execution.**

## A Deeper Dive into Cardiovascular Clinical Development

As a therapeutically-focused CRO with a long history in supporting drugs, biologics, and medical devices for cardiovascular disease, Medpace can provide specialized scientific, regulatory and operational expertise in the design and management of your upcoming studies and programs. We have assembled a team of therapeutically-focused physicians and professional staff who have extensive experience designing and conducting cardiovascular clinical trials and understand the issues from the perspective of the sponsor, the clinical investigator, the scientific leader, and the reviewer at the regulatory agencies. From beginning to end, Medpace can define and execute a clear development plan for your drug, device or combination product.

### Scientifically-driven: In-house Medical Expertise

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 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 addition, Sponsors benefit from cross-over medical expertise from related therapeutic areas such as metabolic and endocrine, respiratory, and autoimmune diseases.

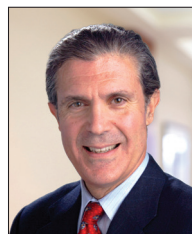
### Nurse Practitioners – Adding perspective through the lens of the patient and site staff

Our medical directors are supported by a team of experienced nurse practitioners 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. Nurse practitioners 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. Nurse practitioners 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.

### Meet Our Physicians



Nicholas Alp, MD, PhD,  
FACC, FRCP  
Vice President, Medical Affairs



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



Marco Tangelder, MD, PhD  
Sr. Medical Director



Thomas G. Todaro, MD,  
JD, FACC, FCLM  
Vice President, Medical Affairs

## EXPERTS

### Nicholas Alp, MD, PhD, FACC, FRCP

*Vice President, Medical Affairs*

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

### Dean Kereiakes, MD, FACC, FSCAI

*Vice President, Medical Affairs*

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

**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

**Thomas G. Todaro, MD, JD, FACC, FCLM***Vice President, Medical Affairs*

Dr. Thomas Todaro is a board-certified Cardiologist with 25+ years of experience in cardiovascular clinical research, drug and device development and direct patient care

**Experience Summary**

- ABIM board certified in Cardiovascular Disease and Internal Medicine
- Fellow, American College of Cardiology
- Former Director of Global Clinical Development at Procter & Gamble; Cardiology lead for Licensing and Acquisitions at P&G
- Global regulatory agency interaction
- Lead Medpace Cardiovascular Core Laboratory (MCCL)
- Manager, global medical teams and international safety hotlines
- Global cardiac trials involving ACS / STEMI / primary PCI/stent, CABG/Valve Surgery, HF, cardiogenic shock, CVA, hypertension
- Former member, New York State Board for Professional Medical Conduct (NYSDOH)
- MD/JD with expertise in medical ethics, IRBs, privacy, informed consent – former IRB member
- Author/co-author of numerous publications and presentations
- Chair, Publications Committee and Member, Executive and Scientific Oversight Committees of the Cardiac Safety Research Consortium (CSRC), a joint collaboration with FDA, academia and industry

**Education Summary**

- Doctor of Medicine (MD), State University of New York (SUNY) College of Medicine – Brooklyn, NY
- Resident and Chief Resident in Internal Medicine, Cardiology Fellow at Nassau University Medical Center (SUNY, Stony Brook) – NY
- Juris Doctor (JD), St. John's University School of Law – Queens, NY
- Executive Education (Integral Leadership), University of Notre Dame, Mendoza College of Business – South Bend, IN
- Bachelor of Science (BS), Manhattan College – Bronx, NY

## EXPERIENCE

The Medpace cardiovascular team has extensive global experience in 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
- Coronary artery disease
- 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

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 united dedication to conducting full-service studies in an exacting manner to produce the highest quality results.

Keys to successful execution include:

- **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:** Due to Medpace's experience and relationships with Investigators and 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.
- **Regulatory Support:** Medpace offers a dedicated global regulatory submissions team as well as global regulatory affairs for comprehensive support.

### Cardiac Safety

In addition to full-service CRO functionality, Medpace's capabilities include core laboratory services in ECG technologies. The Medpace ECG Core Laboratory provides sponsors with reliable, consistent, and prompt electrocardiographic services in support of global clinical development programs to support international Phase I-IV clinical trials. With the intense focus on cardiac safety from regulatory authorities, Medpace also has the integrated services and experts to manage the rigors of TQT studies.

### Who We Are

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.