

## CARDIOVASCULAR CLINICAL DEVELOPMENT

Medpace is a leader in managing cardiovascular drug and medical device trials and has contributed to many of the therapies available today.

Medpace has conducted 300+ CV studies over the last five years.

### Indication Experience

- Acute coronary syndrome
- Coronary artery disease
- Hypertension
- Cardiomyopathies and heart failure
- Arrhythmia
- Atherosclerosis
- STEMI and non-STEMI

### Specialty Areas

- Rare and inherited diseases and orphan indications
- Cell and gene therapies
- Precision medicine
- Pediatrics



### EXPERTS

- In-house medical doctors including board-certified cardiothoracic surgeon and interventional cardiologist
- Advanced Nurse Practitioners provide an additional layer of expertise including patient and site perspectives
- Operational staff with extensive clinical trial management experience
- Regulatory Affairs support at local and global levels

### EXPERIENCE

- Phase I-IV including large global outcome trials
- Management of comorbidities including metabolic disease, diabetes, and obesity
- Adult and pediatric populations
- Variety of study types and designs including acute care, drug/device combinations, large outcome, TQT, CEC, and adjudication processes
- Known for managing complex trials including rare and inherited diseases and orphan indications, cell and gene therapies, and precision medicine

### EXECUTION

- Strong relationships with key opinion leaders (KOLs), investigational sites, cardiovascular networks, advocacy groups, and Academic Research organizations (ARO)
- Global regulatory submissions for faster start-up
- Dedicated Cardiovascular Precision Medicine group for Sponsors employing a precision medicine strategy
- Integrated global laboratory and imaging services
- ECG core lab support
- ClinTrak® study management tool provides IVRS/IWRS, study, data, laboratory, and image management, as well as endpoint adjudication

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## MEDICAL TEAM

Medpace's in-house physicians are embedded within the project team and are fully-involved throughout the study, consulting with Sponsors, Medpace project teams, and the investigative sites to ensure our operational strategy is firmly aligned with the Sponsor's scientific and medical objectives.

## CENTRAL LABS

We offer one of the most extensive selections of biomarkers for cardiovascular, lipid disorder and metabolic disease clinical trials and have CAP accredited labs in the US, Belgium, Singapore and China.

## IMAGING CORE LAB

The ability to streamline imaging and cardiac data management services into the overall clinical trial provides seamless integration and efficiency.

### Capabilities Include:

- Endoscopy
- DXA
- Video and Photography
- ECG/Holter
- ABPM
- Office BP Monitoring

## ECG CORE LAB & CARDIAC SAFETY

Establishing the cardiac safety profile of your compound is critical to success. Through Medpace's wholly-owned cardiovascular core lab, we provide ECG acquisition and analysis services utilizing industry standard devices and systems. As a fully-integrated service, this allows ECG results to be interpreted in the context of all the other data. Our medical, statistical and regulatory specialists ensure all aspects of cardiac safety and efficacy are considered and addressed – including design and consulting, study management, data analysis, and data management.

## DIGITAL TECHNOLOGY & ePRO

Medpace is experienced with both mobile health and digital technologies encompassing a variety of wearables used in clinical trials, such as actigraphy, as well as ePRO.

## SITE NETWORKS & RELATIONSHIPS

Feasibility, start-up and patient recruitment/retention all benefit from our strong relationships with key opinion leaders (KOLs), investigational sites, cardiovascular networks, advocacy groups, and academic research organizations.

## THIRD PARTY VENDOR MANAGEMENT

Medpace can manage third party vendor relationships to ensure efficiency and quality. We provide expectations and define processes for each partner to ensure the successful execution of the trial.

## DATA MONITORING COMMITTEE (DMC) & ADJUDICATIONS

Our Data Monitoring Committee (DMC) and event adjudication group is experienced in the assessment of the safety, scientific validity and integrity of cardiovascular clinical trials. The DMC team is experienced in coordinating with Academic Research Organizations (AROs) performing endpoint adjudication.

## 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.

