MEDPACE

ECG LAB

Experts. Experience. Execution.

Discover the POWER OF X™

Medpace Cardiovascular Core Lab provides expert knowledge plus urgent clinical oversight capabilities for your global trials

The Medpace Cardiovascular Core Laboratory provides state-of-the art, standardized electrocardiogram (ECG) equipment and centralized electrocardiography data analysis to support Phase I-IV clinical trials around the world. Working in collaboration with the medical and regulatory experts at Medpace, the Core ECG team—which includes board-certified cardiologists, ECG technicians, data assistants, and system engineers—has extensive global experience with trial design, data interpretation and analysis, global study management, and regulatory strategy consultation.

Mortara Certified Partner

As a Mortara Certified Partner, the Medpace Cardiovascular Core Laboratory uses state-of-the-art, validated technologies that meet HL7 standards requirements for annotated ECG, 21 CFR Part 11 criteria, and adhere to all US and international regulatory requirements. Our global standard operating procedures (SOP) ensure consistent, efficient, and comprehensive data that meet all Sponsor protocol requirements.

Mortara
CERTIFIED PARTNER

Secure Access

Every digital ECG is read by a board-certified cardiologist who follows strict quality assurance and confidentiality standards to maintain FDA and ICH compliant cardiac safety analysis. All ECG data are fully-integrated into ClinTrak® DM, Medpace's proprietary data management system, or AMPS TrialPerfect database, which enables the Lab to collect, interpret, and distribute cardiac safety and global clinical trial data more efficiently and can provide sponsors access to lab test results and data via a secure, web-based interface.

Why integrate Medpace Cardiovascular Labs into your studies?

The advantages of the Medpace Cardiovascular Core Laboratory include:

- Quantitative and qualitative ECG analysis for single center and multicenter cardiovascular and all other therapeutic clinical trials
- All ECG activities, including site establishment, supplies, training, and data reconciliation and interpretation, are managed through a central data collection point
- All ECGs are read by board-certified cardiologists
- Digital ECGs are captured with state-of-the-art equipment and transmitted electronically to provide greater accuracy and security, and accelerate analysis
- Certified to submit ECG XML data directly to the FDA via Mortara's E-Scribe ECG Warehouse
- Access to ECG data via web-based, ClinTrak DM or AMPS TrialPerfect
- Provides global experience and support

The Medpace Cardiovascular Core Laboratories' capabilities include:

- 12-lead Digital ECGs
- 12-lead Digital Holter Analysis – 24 or 48 hour continuous monitoring of potential arrhythmias, myocardial ischemia, and ST segment analysis
- Alert ECGs reviewed per protocol time requirements
- Non-alert ECGs reviewed within 48 hours
- Customizable Alert Criteria Notification dependent on Sponsor protocols
- Rigorous QT analyses and Thorough QT studies (ICH E14) can be run in conjunction with Medpace's Clinical Pharmacology Unit and its staff clinical pharmacologists, as well as in other CPUs
- Near thorough QT study as part of a first-in-man study

Mortara ELI-150c 12-lead electrocardiograph

Leadership

Thomas Todaro, MD, JD, FACC, Vice President, Medical Affairs-Cardiology, is board certified in Cardiology and Internal Medicine. With over 20 years of clinical and trial experience including 10+ years as director in Global Clinical Development at Procter & Gamble Pharmaceuticals, Dr. Todaro provides medical leadership and oversight to cardiovascular studies.

Kim Barrett, MS, Director of Medpace Cardiovascular Core Laboratory, has been with Medpace for over 10 years and has a strong clinical background as well as data management expertise. She has been global ECG project manager on many studies across a multitude of disciplines including cardiovascular, metabolic, oncologic, and endocrine.

Who We Are

Medpace is a global full-service clinical research organization providing Phase I-IV core development services for drug, biologic, and device programs. With medical and regulatory expertise in multiple therapeutic specialties, Medpace has assembled experienced and therapeutically focused teams to execute at every level of the company's operations, providing complete and seamless drug and device development services.

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