

CARDIOVASCULAR CORE LAB

The Medpace Cardiovascular Core Lab (MCCL) 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.

CARDIOVASCULAR CORE LAB CAPABILITIES

- Quantitative and qualitative ECG analysis for single center and multicenter cardiovascular and all other therapeutic clinical trials
- 12-lead Digital ECGs
- 12-lead Digital Holter Analysis – 24 or 48 hour continuous monitoring of potential arrhythmias, myocardial ischemia, and ST segment analysis
- All ECG activities, including site establishment, supplies, training, and data reconciliation and interpretation, are managed through a central data collection point
- Digital ECGs are captured with state-of-the-art equipment and transmitted electronically to provide greater accuracy and security, and accelerate analysis

MCCL is a leading comprehensive ECG core laboratory, and an integral piece of the Medpace full service CRO product offering. Connected to everything happening globally within the development program, MCCL provides ECG acquisition and analysis services utilizing industry standard devices and systems, which are interfaced with ClinTrak® CTMS. This allows demographic and visit or time point information to be populated from the central database, while providing ECG results to end users in the context of the study as a whole for faster decision making.

MAKING THE COMPLEX SEAMLESS™

EXPERTS

- All ECGs are read by board-certified cardiologists
- In-house registered vascular imaging technologists (RVTs) and echocardiographers (ECHO technologists) with widespread knowledge

EXPERIENCE

- 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
- Near thorough QT study as part of a first-in-man study
- Provides global experience and support

EXECUTION

- 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
- Alert ECGs reviewed per protocol time requirements
- Non-alert ECGs reviewed within 48 hours
- Customizable Alert Criteria Notification dependent on Sponsor protocols



PHASE I/TQT

Thorough QT (TQT) and the recent ICH E14 acceptance of Exposure-QT Response analysis studies as an alternative to a formal TQT study require that a clinical pharmacology team understand the current regulatory environment. This assures a well-designed study for the members of the Phase I Unit and core lab teams to execute. Medpace is a member of the Cardiac Safety Research Consortium, and well versed in the recent updates to the E14 guidelines allowing rigorous ECG assessments in Phase I ascending dose SAD/MAD studies to potentially replace TQT studies. MCCL is located on the same campus as the Medpace Phase I Unit, which provides the optimal environment for cardiac safety studies. Careful planning and execution between MCCL and the Phase I Unit ensures that the Phase I Unit is sensitive to the rigorous requirements surrounding ECG data and that data is available for QC and analysis by the MCCL on demand.

The Medpace Phase I Unit utilizes the Mortara Surveyor 12-lead telemetry system, which provides the highest quality ECG data available for complex, ECG intense studies. The Phase I Unit provides MCCL with high resolution, continuous 12-lead ECG data, allowing for the detection of a 1ms change, with a 10ms shift from baseline being the threshold for regulatory concern. A board-certified cardiologist who follows strict quality assurance and confidentiality standards to provide FDA-, EMEA-, and ICH-compliant ECG safety analysis reads every digital ECG. As a Mortara Certified Partner for ECG submission to the FDA ECG Warehouse, the MCCL uses state-of-the-art, validated technologies that meet international regulatory requirements.

PHASE II-IV

Medpace has global operations and the logistics expertise to efficiently move and support the equipment for centralized ECG studies wherever needed. Localization of settings and hardware for each device is performed prior to shipment, so that the equipment is ready when delivered. Transmissions of test ECGs are made with the site support team upon receipt of each device, and primary site support contact is established for any further support needs.

The latest generation Mortara ELI 150c devices are used, which provide data encryption not found on earlier devices, ensuring secure global transmission to the MCCL data center. These devices also allow integration with the ClinTrak enrollment database, which eliminates demographic data entry on the devices. No data entry eliminates the majority of site queries, which can be much higher than ECGs transmitted without database integration.

Global standard operating procedures (SOPs) are in place to ensure consistent, efficient, and comprehensive data that meets all Sponsor protocol requirements. Measurement and annotation of ECGs is provided utilizing multiple industry standard methodologies; Manual Adjudication, Semi-Automatic or Fully Automatic, depending on client need and budget. Sponsors are provided access to ECG data via web-based, Medpace ClinTrak DM.

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.

