MEDPACE

CARDIAC SAFETY

Conducting Thorough QT (TQT) studies implemented under ICH E14 guidelines requires an exceptional level of coordination and control. Medpace, with integrated services and cardiac safety experts all housed on the same clinical research campus, provides a distinct advantage for managing the rigors of TQT studies. Our drug development expertise coupled with an integrated approach to studying cardiac safety delivers complete control and greater efficiency for your study.

With the intense focus on cardiac safety from regulatory authorities, it's important to entrust your TQT study to a highly qualified team that can provide the guidance and insights to move your product development forward. Early planning is especially critical. Medpace's therapeutically-focused medical monitors, regulatory experts, clinical pharmacologists, and statisticians work collaboratively to review protocols and provide guidance for study design and regulatory submissions. This early involvement can lead to cost savings and efficiencies throughout the development cycle.

Key support Services:

- Cardiovascular core lab services can be used as an integral piece of the Medpace full-service CRO product offering, or as a stand-alone service
- Full resources of a global CRO
- In-house physicians and cardiology specialists with excellent peer to peer relationships with KOLs
- Extensive global experience with trial design, data interpretation and analysis, study management, and regulatory strategy consultation
- Phase I-III capabilities for multi-centers and global studies
- ECG acquisition and analysis services utilizing industry standard devices and systems, allowing ECG results to be interpreted in the context of all the other data Medpace

MAKING THE COMPLEX

SEAMLESS™

EXPERTS

- Led and supported by a team of nationally recognized cardiologists
- All ECGs read by board-certified cardiologists
- PhD statisticians trained in TQT studies
- Highly qualified technicians specially trained to the rigors of TQT studies
- Dedicated ECG program managers for single point of contact

EXPERIENCE

- Medpace operations in over 50 countries ensure your study will receive the attention needed, should higher than normal levels of support be required
- Medpace global equipment logistics experience ensures your devices will arrive at investigator sites when and where needed, without customs or duties related delays

EXECUTION

- Medpace validation of systems ensures proper qualification of tools and methodology
- The Medpace team will compile the statistical results and medical conclusions and medical writing services needed for regulatory submission, and if required, work with your team to present the data to regulatory agencies
- 24/7x365 Technical Support is available, ensuring timely resolution of support needs
- 60,000 sq.ft. Phase I Unit on campus with systems designed for TQT studies tightly integrated with the core lab

TECHNOLOGY

Medpace is a Mortara Certified Partner. We use 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 12-lead ECG Surveyor Telemetry Central System with 32 telemetry channels
- Mortara ECG 12-lead holters
- Mortara 12-lead ECG machines
- Access to ECG data via Medpace's proprietary web-based ClinTrak™ DM or AMPS TrialPerfect™
- Digital ECGs are captured with equipment and transmitted electronically to provide greater accuracy and security, and accelerate analysis
- Certified to submit ECG XML data directly to the FDA ECG Warehouse

ECG CORE LAB

Medpace Core Labs are comprised of cardiac safety and imaging core supporting trials across a broad range of therapeutic areas. The Imaging Core Lab offers expertise in a broad range of imaging modalities and provides services for either stand-alone or fully integrated projects with Medpace full-service, scientifically-driven clinical teams. Our integrated core labs provide an end-to-end suite of global imaging services to enhance and expedite biopharmaceutical and medical device development. This complements the state-of-the art, standardized electrocardiogram (ECG) equipment to support Phase I-IV clinical trials around the world.

CPU

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 understands the current regulatory environment to assure 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 updates to the E14 guidelines allowing rigorous ECG assessments in Phase I ascending dose SAD/MAD studies to potentially replace TQT studies.

- Phase I Unit located on the same campus as MCL, providing an optimal environment for cardiac safety studies
- Sensitive to requirements surrounding ECG data and ensures that data are available for analysis on-demand
- Utilizes the Mortara Surveyor 12-lead telemetry system, providing the highest quality ECG data available for complex, ECG intense studies

BIOANALYTICAL LAB

Leveraging state-of-the-art instrumentation, techniques, and facilities, our team of experts has experience in a broad range of small and large molecule bioanalytical and biomarker support. Working in a good laboratory practice (GLP) compliant setting, the Medpace Bioanalytical Laboratories provide method development, transfer, validation, and analysis of preclinical and clinical biological samples. We have extensive expertise in developing sensitive methods for LC-MS/MS–qualifying multiple-analytes, metabolites, prodrugs, and light- and temperature-sensitive compounds. Our discovery team regularly supports fast PK, bioavailability, and early toxicology studies.

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.

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