MEDPACE

CARDIAC SAFETY

Experts. Experience. Execution.

Discover the POWER OF X™

TQT Studies

Medpace's drug development expertise coupled with an integrated approach to studying cardiac safety delivers complete control and greater efficiency

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.

A Collaborative Team that Understands the Challenges and Hurdles

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.

A Controlled Environment Means Better Data

In conducting the study, Medpace is able to orchestrate with absolute precision. With our state-of the art clinical pharmacology unit and cardiac safety experts all located on the same campus, we are able to take total control of the testing environment. The proven result is improved data collection.

Why Medpace?

Medpace offers a comprehensive solution for TQT studies.
Our integrated services on the Medpace Clinical Research Campus in Cincinnati, OH USA deliver complete control and greater efficiency:

- Medpace ECG Core Lab
- Medpace Clinical Pharmacology Unit
- Medpace Bioanalytical Laboratories
- Medpace Reference Laboratories
- Medpace Clinical Research Organization

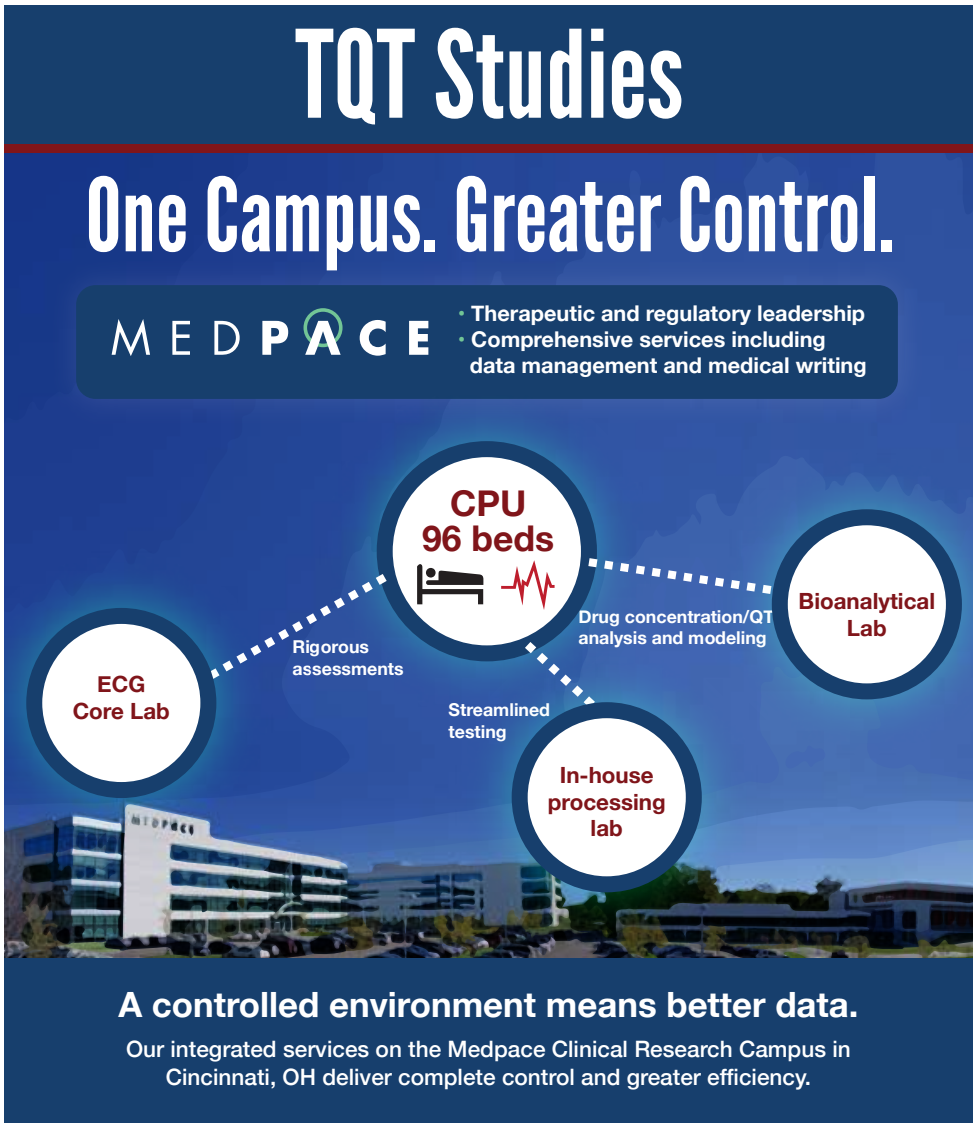
Led by board-certified cardiologist

All ECGs read by US board-certified cardiologists

PhD statisticians trained in TQT studies

Highly qualified technicians specifically trained to the rigors of TQT studies

Dedicated ECG program manager for single point of contact



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 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 ECG Warehouse

Cardiac Safety - Looking Forward

There clearly will be an ongoing emphasis on cardiac safety and proarrhythmia risk assessments within clinical research. Medpace, and its team of medical, regulatory, and clinical professionals, are keenly aware of and involved in this evolution. For example, Dr. Tom Todaro, Vice President, Medical Affairs, Cardiology and ECG core laboratory, is a member of the Scientific Oversight Committee of the Cardiac Safety Research Consortium, a joint collaboration with the FDA, academia and industry. Looking forward, Medpace is committed to providing Sponsors with ongoing leadership and quality in cardiac safety.

Contact Medpace

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