



Thorough QT (TQT) Studies

The prevalence of cardiovascular side effects observed with many of today's therapeutics has resulted in increased regulatory and industry awareness for cardiac safety monitoring. Formal guidance (ICH-E14) requires sponsors to assess new drugs for pro-arrhythmia risk using a formal Thorough QT (TQT) study.

TQT studies are complex and challenging as they measure very small changes in mean QT values (5-10 ms), require statistical corrections for heart rate, and must account for natural variation of QT intervals between subjects.

WHEN DESIGNING A TQT STUDY, SPONSORS MUST CAREFULLY PLAN FOR:

- selection of study population
- appropriate sample size
- correct doses and dosing regimens
- choice of baseline
- standardized ECG recordings
- blinded ECG analysis and overread

CHOOSE BIOCLINICA FOR YOUR NEXT TQT STUDY

- › Global leader in centralized ECG services and TQT study design
- › Thousands of clinical trials supported over nearly three decades
- › Scientific and Medical expertise including board-certified cardiologists
- › Expertise and guidance for regulatory submission
- › Continuous, year-round investigator support



BioClinica is proud to have conducted the first TQT studies in Japan and China.

CONCEPT AND PROTOCOL DESIGN

- › Extensive knowledge of study parameters and design
- › Full protocol and SAP development
- › Identification of clinical pharmacology research units

We are the only core lab to have developed a novel TQT study design which allows sponsors to substantially cut study size and cost.

ECG COLLECTION AND STATISTICAL ANALYSIS

- › Advanced ECG data capture
- › Innovative ECG data management
- › ECG analysis by board certified cardiologists
- › On staff statistical expertise
- › Selection of QT corrections
- › Controlling for QT:RR hysteresis
- › Concentration effect modeling (PK:PD)

EXPERT REPORTING

- › Medical and Statistical Cardiac Safety Report
- › Interim Cohort reporting
- › QT reports
- › Expertise with regulatory submission strategies (FDA, EMA, PMDA, CFDA)

SCIENTIFIC EXPERTISE

A dedicated team focused on your needs provides expert cardiac safety analysis, high quality data and regulatory reporting. We understand that each study is unique and our scientific experts work with you to provide an effective cardiac safety solution to meet your study goals.



Boaz Mendzelevski, MD
Vice President, Cardiology

Dr. Mendzelevski is a board certified cardiologist with training in Interventional Cardiology and Clinical Electrophysiology. He brings a wealth of scientific and regulatory expertise for the design and implementation of TQT studies globally and the emerging cardiac safety landscape in Asia. Dr. Mendzelevski has authored approximately 250 expert reports in support of NDA regulatory submissions and sits on several pharmaceutical advisory boards.



Jeff Heilbraun, MS
Vice President of Strategic Development

Jeffrey Heilbraun has over 20 years of experience with the science and physiology of cardiac safety within the pharmaceutical sector. His expertise is focused on hemodynamics and the implementation of blood pressure endpoints for cardiac safety studies. Jeff regularly presents at scientific meetings, is an active member of the Cardiac Safety Research Consortium and the MCC Cardiopulmonary performance metrics group and has co-authored peer reviewed articles on cardiac safety.

INNOVATIVE TECHNOLOGY

BioClinica's Cardiovascular Services are built on an innovative technology called WebHeart®, a proprietary, web-based, 21 CFR part 11 compliant and configurable platform for the acquisition, management, analysis and reporting of cardiovascular safety and efficacy data.

Features and benefits of the WebHeart platform include:

- Rapid and real-time management of ECG data via secure internet access
- Configurable for sponsor-specific protocols
- Compatibility with all ECG and ABPM technologies and operating systems
- Centralized storage of cardiovascular data
- Regulatory submission-ready ECG data (Mortara® certified and annotated XML files)
- Role-based, 'rights-restricted' security model
- No special software, plug-ins, or add-ons required



About BioClinica

BioClinica accelerates the development of new medical therapies by delivering expertise and technologies that enhance clinical research, worldwide. Our industry-leading medical imaging services, cardiovascular safety, and enterprise eClinical platform bring a new level of quality and efficiency to every phase of clinical development. Our experience spans three decades and includes thousands of studies in all therapeutic areas, from design and management, through submission and post-approval. BioClinica serves more than 400 pharmaceutical, biotechnology, and device companies – including all the top 20 – through a network of offices in the U.S., Europe, and Asia.

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