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## **CARDIOCORE and ROCHE Join Forces to Contribute Unique Data to the URMCFDA Holter ECG Warehouse**

### **THEW, Roche and Cardiocore Collaboration Enables Key Cardiac Safety Research Milestone**

The Telemetric and Holter ECG Warehouse (THEW) is a cardiac research initiative developed by the University of Rochester Medical Center (URMC) in partnership with the Food and Drug Administration (FDA). Today, THEW administrators announced that Roche shared data from a recently completed Thorough QT study (TQT), with Cardiocore being the first core lab to successfully format Holter ECG data for upload to the THEW repository.

As part of their continuing collaboration with Roche, Cardiocore acquired and analyzed the data during a 2008 TQT. To prepare the continuous electrocardiographic recordings for THEW submission, Cardiocore administered Roche's custom specification for data de-identification.

"We are delighted to contribute these data to the THEW program," said Ignacio Rodriguez, MD, head of Roche's ECG Working Group. He continued, "We hope that this data will help advance the science of cardiac safety monitoring. In striving for innovation, we are fortunate to work with like-minded and supportive partners at the THEW and Cardiocore."

In this Roche TQT, Cardiocore analyzed more than 300 recordings of 24-hour Holter data that were acquired from 76 subjects in a crossover design. Cardiocore deployed high-fidelity devices that record continuous electrocardiographic data at 1,000 samples per second, enabling true one-millisecond resolution during analysis. Fully de-identified data from the placebo and positive control periods were shared.

The THEW director, Dr. Jean-Philippe Couderc, PhD commented, "Roche has shared, with the help of Cardiocore, a scientifically relevant set of information. Their successful submission of both clinical and ECG information to our international repository solidifies our legal framework for data sharing. More importantly, this data will enable unique research projects for validating and improving precision of current and future ECG technologies. THEW partners will be able to access these Holter ECGs from which more than 2 million standard 12-lead ECG tracings can be extracted. We are glad to recognize both Roche and Cardiocore as pioneering data contributors to our initiative."

**About THEW:** *The Telemetric and Holter ECG Warehouse (THEW) is a not-profit organization hosted at the University of Rochester (UR) Medical Center (NY). The THEW is a research platform for sharing data, tools and expertise for the development of ECG-related technologies. The THEW benefits from the scientific and technical heritage of the Heart Research Follow-UP program which has more than 20 years of research experience in quantitative analysis of ventricular repolarization involving animals, normal subjects, patients with genetic (Long QT Syndrome) and acquired cardiac disorders. Striving to advance the field of cardiac safety, the THEW initiative is developed under an agreement with the Food and Drug Administration for facilitating collaborative discussions between THEW members, and for leveraging resources to implement joint projects among FDA, UR, and other public and private stakeholders. The THEW is led by individuals from the UR, the Commissioner Office of the FDA, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health. More information can be found at [www.thew-project.org](http://www.thew-project.org).*

**About Cardiocore:** *Cardiocore has provided superior centralized cardiac testing services to the pharmaceutical industry for 15 years. Services include centralized electrocardiographic (ECG) analysis, Holter monitoring, echocardiography, statistical analysis and consulting services such as protocol design. The company is experienced in both the design and the implementation of cardiac safety and efficacy testing in Phase I, II, III and Thorough QT clinical trials. These services are supported by the company's CardioCorrect® system featuring the proprietary HolterGateway™ and CardioPortal™. Cardiocore's U.S. headquarters is located in Bethesda, Maryland, its West Coast office is located in San Francisco, California, and its European subsidiary, Cardiocore Limited, is located in London, England. [www.cardiocore.com](http://www.cardiocore.com)*