URMC, FDA to Collaborate on National Data Repository for Heart Research

The University of Rochester Medical Center (URMC) will collaborate with the U.S. Food and Drug Administration (FDA) to develop a national repository of data that will aid academic and industry researchers studying the electrical activity of the heart. In addition to helping researchers understand many cardiac problems, the data may aid the development of new tools to detect drugs that can have dangerous effects on the heart.

The repository will include thousands of electrocardiogram (ECG) recordings from cardiac patients and healthy volunteers who have worn small devices to monitor their heart activity, usually for hours or days at a time. It includes ECG recordings of rare events, including dangerous heart-rhythm problems that were triggered by certain drugs.

Researchers at URMC have been collecting and studying the ECG data for decades through the university's Heart Research Follow-Up Program. The data repository, which will be owned and maintained by URMC, will be called the Telemetric and Holter Electrocardiogram Warehouse, or THEW. An agreement signed by URMC and FDA establishes both parties' intent to work together, under the auspices of a public-private partnership, to use the THEW data to address public health needs in the area of cardiac safety.

Access to the THEW data by outside researchers will be governed by an executive committee that includes representatives from URMC, FDA, industry, academia, and other stakeholders. Representatives from FDA will provide scientific input on research projects aimed at improving drug safety, such as identifying patterns in ECG data that reveal drug side effects, and the development of computer software that scan large amounts of ECG data to spot those patterns.

"The goal of this program is to give companies and not-for-profit organizations the ability to develop and validate new technologies and advance the field of quantitative electrocardiology," said URMC biomedical engineer Jean-Philippe Couderc, Ph.D., the director of the THEW project. "Current methods of measuring a drug's potential toxicity to the heart are insufficient. Scientists need access to more data so they can develop a better picture of what is going on in patients across time so we can do better measurements with more precision."

"The opportunity to interact with Dr. Couderc and the University of Rochester is important for at least two reasons," said Norman Stockbridge, M.D., director of FDA's Division of Cardiovascular and Renal Products. "First, they are accumulating unique data that will be useful in understanding how certain cardiac risks can be revealed by specific changes seen on the electrocardiogram. Second, Dr. Couderc and his colleagues bring valuable expertise in identifying properties of the ECG tracing that reveal whether a drug is causing a specific side effect, or that reveal a patient's susceptibility to dangerous heart arrhythmias."

Sudden cardiac arrest is the leading cause of death in the United States, resulting in over 450,000 deaths per year. One mechanism of cardiovascular death is related to drugs triggering a predisposition to lethal cardiac arrhythmias or by the drugs themselves. As part of FDA's regulatory review, the agency requires evidence of a drug's impact on the QT interval as one way to assess the cardiac risk associated with new compounds. The QT interval is a segment of an ECG recording that measures the

process of ventricular repolarization – the period between the heart's contraction and recovery phase. If a drug prolongs the repolarization process, then it is generally believed to heighten the risk for adverse cardiac events. Prolongation of the QT interval associated with episodes of fatal ventricular arrhythmias is a leading cause of removal of drugs from the market and was a leading impetus toward international collaboration to develop specialized studies to monitor the QT prolongation effects of new drugs

The THEW will be housed at URMC's Heart Research Follow-up Program. The program is anticipated to be an international effort in the science of heart arrhythmias and a rare genetic condition associated with an abnormal QT interval, called the congenital Long QT Syndrome (LQTS). The university keeps an International Registry for LQTS, and follows thousands of families who have this inherited condition. One of the genetic forms of the QT prolongation syndrome is similar to the drug-induced syndrome, and the university's work focuses on developing the tools to identify individuals with either condition.

THEW website: http://www.thew-project.org/