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Pfizer Contributes Critical Data to URM C Drug Safety Initiative

Pfizer has agreed to provide the University of Rochester Medical Center (URMC) with a unique set of electrocardiographic data that will help researchers develop new methods to ensure the safety of experimental drugs. This is the first time a major pharmaceutical company has agreed to publicly share anonymous data from one of its drug safety trials, including data from the drug that was being evaluated.

Pfizer Global Research and Development's Sandwich Laboratory in the United Kingdom is releasing a large set of continuous electrocardiographic (ECG) recordings to URM C from which more than 1.5 million individual ECGs datasets can be extracted.

A full set of study data, which Pfizer is providing, is extremely valuable because it enables scientists to evaluate the electrical activity in the heart before and after study participants took the drug and compare that data to study subjects who received a placebo or a control drug that is known to prolong the repolarization process.

Earlier this year, URM C announced that it was collaborating 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. The resulting database, called the Telemetric and Holter ECG Warehouse (THEW), consists of a digital catalogue of continuous recordings from both cardiac patients and healthy individuals and is available to academic researchers, pharmaceutical companies, contract research organizations, device manufacturers, and other interested parties.

The Pfizer data, in compliance with the local and international ethics and patient privacy laws, has been fully anonymized, or stripped of any information that would enable individual patients to be identified. Additionally, the THEW was designed in order to comply with ethics and patient privacy laws; all data in the warehouse have been de-identified and the system is fully compliant with federal privacy (HIPPA) regulations.

"We are glad and thankful that Pfizer has chosen the THEW platform for sharing their data with the international scientific community" said Jean-Philippe Couderc, Ph.D., director of the THEW initiative. "We believe the global strategy of our initiative, its legal framework, and the support received from the Food and Drug Administration have played key roles in the development of successful collaboration with companies like Pfizer."

The Pfizer data will be housed in THEW and will enable researchers to develop new tools to detect drugs that may have dangerous effects on the heart. The Pfizer data will consist of several important sets of ECGs from different phases of a study of a drug that did not reach the market because of its adverse effect of the process of cardiac ventricular repolarization – the split second 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, such as dangerous arrhythmias and heart attacks.

Sudden cardiac arrest is the leading cause of death in the United States, resulting in over 450,000 deaths per year. Included in this number are deaths caused by drugs that trigger a predisposition to lethal cardiac arrhythmias or even the drugs themselves. As part of FDA's regulatory review process, 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. 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 project is part of this initiative.

The THEW database is a component of URMIC's Heart Research Follow-up Program. The Program is an international leader in the science of heart arrhythmias and a rare genetic condition associated with an abnormal QT interval, called the congenital Long QT Syndrome (LQTS). URMIC 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/>