

AstraZeneca Joins Rochester Initiative to Further Cardiac Safety

September 22, 2010



Jean-Philippe Couderc, Ph.D., with ECG technician Betty Mykins

AstraZeneca purchased a one-year membership to gain access to an international repository of data designed to aid industry and academic researchers developing new technologies to improve cardiac safety. The database, called the <u>Telemetric and Holter</u> <u>ECG Warehouse</u> (THEW), helps researchers better evaluate how drugs affect the heart. Cardiac toxicity is one of the leading causes of removal of drugs from the market today, which is why ongoing research in this area is needed.

THEW is the result of a partnership between the University of Rochester Medical Center, the U.S. Food and Drug Administration (FDA) and the National Heart, Lung and Blood Institute (NHLBI) of the National

Institutes of Health. THEW consists of a digital catalogue of continuous electrocardiographic recordings from cardiac patients and healthy individuals, as well as electrocardiograms from safety studies implemented by major pharmaceutical companies.

In addition to helping industry and academic researchers better understand the electrical activity of the heart and how individual drugs may influence this activity, the data may aid the development of new tools to more easily detect drugs that can have dangerous effects on the heart. With the THEW partnership, AstraZeneca will gain full access to a wide range of electrocardiographic recordings and the associated clinical information that can be used to develop, implement and validate electrocardiographic markers of drug cardiotoxicity.

"We believe AstraZeneca's interest and involvement in our initiative is an important milestone. The support we have received from major pharmaceutical companies has grown over time and further validates our decision to develop a repository for scientific data for the development of novel technologies related to cardiac safety," said associate professor in the Division of Cardiology at the University of Rochester Medical Center and director of the THEW project.

Companies may purchase a year-long, full-access membership, or they may purchase access to individual databases within THEW. Membership information can be found on the THEW website at <u>www.thew-</u>project.org.

"We are glad to generate opportunities for pharmaceutical companies to evaluate their cardiac safety technologies using the data from our repository. Over the past two years, we have helped companies improve their ECG tools and several of these tools have had a profound impact on the way companies assess cardiac safety," said Couderc.

The THEW database is part of the Center for Quantitative Electrocardiography and Cardiac Safety, which is a component of URMC'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). URMC 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

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syndrome is similar to the drug-induced syndrome, and the university's work focuses on developing the tools to identify individuals with either condition.

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