

THEW eNewsletter, issue 1, July 2008:

This electronic Newsletter is a publication with updates about the activities of the Telemetric and Holter ECG Warehouse (THEW) Initiative at the University of Rochester (UR), NY.

EDITORIAL

July 2008 –The University of Rochester and the FDA sign a collaboration agreement .

The THEW team at University of Rochester (UR) is glad to announce that a collaborative agreement with the FDA has been signed by the UR and Dr. Janet Woodcock, Director of the CDER, and Dr. Norman Stockbridge, Acting Director of the Cardio-Renal Division of the CDER on May 27th, 2008. This marks the official start of the collaboration between the THEW and the Agency and is accompanied by a Confidentiality Disclosure Agreement to create an appropriate legal framework.

The THEW concept emerged during a meeting I had with Dr. Stockbridge in December 2007. The idea was to create a warehouse for Holter and continuous ECG recordings in order to evaluate their contribution to the assessment of QT prolongation in drug safety studies. On January 16th, 2008, the first THEW meeting co-organized by Dr. Norman Stockbridge and myself, was held on the FDA-campus in Silver Spring, MD. Various pharmaceutical companies, Contract Research Organizations, ECG equipment companies and Universities attended this First THEW event to learn about our initiative. This conference included a scientific session with presentations from Research and Development executives of some of the world leading companies in the fields of quantitative electrocardiography.

On March 15th, 2008, the THEW website was released (www.thew-project.org) providing a comprehensive description of the expertise, the data and tools available through the THEW initiative. One month later, the THEW Donation program started and received generous financial support from large pharmaceutical and ECG equipment companies, as well as from CROs.

This large momentum around the development of the THEW project has remained strong during the past 6 months and is expected to grow more with upcoming research projects that the THEW team and members are developing. The purpose of this newsletter, is to keep you informed about the recent developments and the various opportunities that may be of interest to your organization.

Finally, we would like to thank the companies which contributed to the THEW initiative by either providing financial support or by sharing technology (or both). We strongly believe that this project will contribute to develop better life-saving tools, specifically in the field of drug safety research and in the overall cardiac safety arena.

Sincerely,
Jean-Philippe Couderc. PhD

Website: THEW-project.org
Email: thew@heart.rochester.edu
FDA Press Release: <http://thew-project.org/document/THEW-FDA1.pdf>

FDA - University of Rochester Collaborate

On May 27th, 2008, Dr. Janet Woodcock (Director, Center for Drug Evaluation and Research U.S Food and Drug Administration) and Dr. Norman Stockbridge (Acting Director Division of Cardiovascular and Renal Products Center for Drug Evaluation and Research U.S. Food and Drug Administration) have signed a Letter of Agreement officially starting a 3-year partnership between the FDA and University of Rochester related to the THEW initiative. The letter of agreement describes the legal framework for the collaboration and is accompanied by a fully executed Confidentiality Disclosure Agreement.

Learn more at: www.thew-project.org/mission.html

Download the Press Release including FDA quotes:

<http://thew-project.org/document/THEW-FDA1.pdf>

THEW Founding Donation Program

The THEW released its Founding Donation Program in January 2008. Several companies from Europe and US have joined the program. They include pharmaceutical companies, contract research organizations, and ECG equipment companies. Several of these companies have also committed to contribute to the THEW by sharing data or/and technologies.

The list of companies can be found at

www.thew-project.org/contributors.html
