

Telemetric and Holter ECG Warehouse, Issue 2, September 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.

THEW Update - September 2008 – Development of the THEW: Executive Committee, Governance Structure and Validation of the Thew Client Application.

These past months have been very busy for the THEW team. Amongst the list of action items completed during September and August 2008, we would like to highlight three important milestones: the formation of the Executive Committee of the THEW, the completion of the THEW Governance Structure and the validation phase of the beta-version of the THEW Client Application.

First, we are glad to announce the list of members of the THEW Executive Committee; it includes individuals from the University of Rochester and its Medical Center, the Center for Drug Evaluation and Research (CDER), the Center for Devices and Radiological Health (CDRH), and the Office of the FDA Commissioner. The list of the members is described below and on the THEW website (www.thew-project.org/aboutus.htm).

Second, the Governance structure of the THEW initiative has been completed with the help of Dr. Wendy Sanhai, Senior Scientist at the FDA Commissioner Office, Dr. Benjamin Eloff from the CDER and Gail Norris, Director of the Office of Counsel of the University of Rochester, NY. This document provides detailed description of the THEW, the various processes around data and research proposal submissions, and the responsibilities of the different committees.

Finally, we have successfully completed the first validation phase of the THEW Client Application. The FDA has contributed to this validation phase involving representatives from the CDER and the CDRH. Also, the beta-version of the software has been distributed to a selected number of Academic Centers in Europe (Italy, France, Czech Republic, and Finland) and in the United states (MD, DC, and NY). We would like to thank the FDA team and our National and International Network of Academic Investigators for their feedback.

Jean-Philippe Couderc, PhD
Director of the Telemetric and Holter ECG Warehouse Initiative

In-depth...

- The THEW has formed its Executive Committee

We are glad to announce that the Executive Committee of the Telemetric and Holter ECG warehouse has been formed. The responsibilities of the EC are to define and ensure the objectives of the THEW program in accordance with its mission, to ensure the development of logistics and operational infrastructure of the THEW, and finally to review, approve and execute plans, to establish and oversight the Scientific Committee (SC), Data Review Committee (DRC) and the Translational Research Group (TRG).

The members are described in details :

Dr. JP. Couderc (URMC).
Dr. B. Eloff (CDRH, FDA),
Dr. AJ. Moss (URMC)
G. Norris (UR),
Dr. W. Sanhai (Commissioner Office, FDA),
Dr. N. Stockbridge (CDER, FDA),
Dr. W. Zareba (URMC)

More information here: <http://www.thew-project.org/aboutus.htm>

- The THEW Governance structure is available on the website

The design of the THEW governance has been completed in collaboration with Dr. Wendy Sanhai (FDA), Dr. Benjamin Eloff (FDA), and Gail Norris (UR). The governance describes the structure of the THEW initiative and the various processes around data submission, research proposal submission and other information important to the partners of our exciting endeavor.

More information here: <http://www.thew-project.org/download.html>

The beta-version of the THEW Client Application (V1.0.0.4) tested on site at the FDA and in seven beta-sites in the U.S. and in Europe

This last week of August, the beta-version of the THEW Client Application (CA) has been released to a selected number of sites in the United States (MD, DC, and NY) and in Europe (Italy, France, Czech Republic, and Finland) leading to an International effort for the validation of our software. In addition, the FDA was part of this validation process and individuals from the CDER (Dr. Mike Li, and Dr. Suchitra Balakrishnan, FDA Campus, Silver Spring, MD) and from the CDRH (Dr. Benjamin Eloff) were involved in this process

More information about the THEW Client Application here:
<http://www.thew-project.org/content.html>