TELEMETRIC and HOLTER ECG WAREHOUSE, ISSUE 5, SEPTEMBER 2009:

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 awarded by the National Heart, Lung and Blood Institute (NHLBI)

- THEW announces the "Beyond QT" Working Group

- Secured THEW FTP server up and running

THEW awarded by the NHLBI: The THEW announces a multi-million dollar award from the National Heart, Lung and Blood Institute (NHLBI) obtained through an investigator-initiated R24 submission. Officially released by the Institute on Monday September 12, this award will be used for the development of the "Center for Quantitative Electrocardiography and Cardiac Safety" (R24HL096556). The Center will host the Telemetric and Holter ECG Warehouse (THEW) and its activities. In addition, this grant will support the expansion of the current infrastructures and fund future scientific activities utilizing the data from the THEW. Dr. Jean-Philippe Couderc, Principal Investigator commented:" This award represents a new cornerstone for our project. First, it will enable us to expand our team, to enhance the level of security of the warehouse, and more importantly to allocate resources to grow significantly the list of datasets available in the warehouse. With this R24 award, the NHLBI has recognized the scientific potential of our project and has committed to be involved in our endeavor." According to Dr. Couderc, the NIH proposal was submitted with supporting letters and research proposals from more than twenty organizations including US and European academia as well as several major pharmaceutical companies.

THEW "Beyond QT" Working Groups: Following the success of the THEW Meeting at the FDA Campus in May 2009, the THEW has formed a working group consisting of world experts and members of the THEW to discuss the current and the future of ECG technologies in drug safety trials. This group has regular conference calls hosting FDA representatives such as Drs. Stockbridge (CDER), Ricci (CDRH) and Goodsaid (CDER). The group started working in June 2009, on the definition of strategic paths around the qualification of new ECG markers for drug safety trials. The working group discusses on a regular basis with regulators and includes public and private partners interested in the development of novel tools for drug safety trial related to quantitative electrocardiography.

Secured THEW SFTP server up and running: The University of Buffalo has opened, in collaboration with the <u>NYSTAR</u> program, the THEW Secured FTP Server for the distribution of the data from the THEW. The Server is up and running and contains 350 MB of data including the following databases: E-HOL-140-001, E-HOL-273-002, E-HOL-

206-003, E-HOL-175-005, E-HOL-12-280-008 and E-OTH-12-6-009. The descriptions of these databases are available at <u>http://thew-project.org/database.html</u>.