The Telemetric and Holter ECG Warehouse (THEW) Project

Concept and Progress

Thew (thew) n. (thu): qualities of mind; disposition; specifically, good qualities; virtues

Webster's Revised Unabridged Dictionary
Thew (thew) *n.* (thū): Manner; custom; habit; form of behavior; qualities of mind; disposition; specifically, good qualities; virtues

Webster's Revised Unabridged Dictionary
The objective of the *Telemetric and Holter ECG Warehouse (THEW)* is to provide access to continuous electrocardiographic data to for-profit and not-for-profit organizations for the design and validation of analytic methods to advance the field of quantitative electrocardiography with a strong focus on cardiac safety.
University of Rochester and FDA Partnership:

“The THEW project is considered important by the Food and Drug Administration in view of its potential to support academic research towards the design and validation of analytic methods to advance the field of quantitative electrocardiography with a strong focus on drug cardiac safety. The key element of a partnership with the URMC is currently being discussed with FDA as a project for incorporation under FDA’s Critical Path Initiative.” ….

“One of the goal of the THEW project will be to provide access to continuous electrocardiographic data to for-profit and not-for-profit organizations/entities to support the aforementioned goals in the context of cardiac safety.”
• **Provide Access to Valuable Holter ECG Data for R&D Activities**
  • Cardiac patients (CAD, AMI)
  • Healthy individuals
  • Drug–induced arrhythmias
  • Congenital LQTS

• **Deliver Tools for ECG Data Access and Visualization (THEW Client Application)**
  • Continuous ECG visualization tool
  • Holter annotation information

• **Open Tools for the Development of Application Programming Interfaces (APIs) compatible with the THEW Client Application**

• **Share technologies using an API Library**

• **Access to ECG metrics**
  • HRFUP-URMC ECG metrics
  • Holter annotation full review
## THEW Content

<table>
<thead>
<tr>
<th>Study</th>
<th>ECG type</th>
<th>Contributor</th>
<th># recordings</th>
<th>Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDEAL 1</td>
<td>24-hour Holter</td>
<td>HRFUP</td>
<td>108</td>
<td>Acute Myocardial Infarction</td>
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<tr>
<td>IDEAL 2*</td>
<td>24-hour Holter</td>
<td>HRFUP</td>
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<td>Healthy Individuals</td>
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<td>IDEAL 3</td>
<td>24-hour Holter</td>
<td>HRFUP</td>
<td>294</td>
<td>Coronary Artery Patients</td>
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<tr>
<td>Acqu. LQTS</td>
<td>24-hour Holter</td>
<td>Munich University</td>
<td>3</td>
<td>Drug-induced torsades de pointes</td>
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<tr>
<td>Cong. LQTS 1</td>
<td>24-hour Holter</td>
<td>Munich University</td>
<td>4</td>
<td>Genotyped, torsades de pointes</td>
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<td>Sotalol</td>
<td>24-hour Holter</td>
<td>Pfizer Inc.</td>
<td>99</td>
<td>baseline, single and double dose of sotalol (160/320 mg)</td>
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<tr>
<td>Dofetilide</td>
<td>24-hour Holter</td>
<td>Pfizer Inc.[1]</td>
<td>5,000</td>
<td>Several drug-induced TdPs and ventricular arrhythmias</td>
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<tr>
<td>Moxifloxacin</td>
<td>24-hour Holter</td>
<td>GSK[2]</td>
<td>~100</td>
<td>Thorough QT study</td>
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<td>Cong. LQTS 2</td>
<td>24-hour Holter</td>
<td>HRFUP</td>
<td>70</td>
<td>Genotyped</td>
</tr>
</tbody>
</table>

[1] Pfizer agreed on sharing the data for THEW, legal aspect around the data sharing are being discussed.  
[2] GSK agreed on sharing the data for THEW, legal aspect around the data sharing are being discussed.  
* Data available for the pilot study
Architecture

Members:
- Pharmaceutical/ECG companies
- CROs
- Academic centers
- CSRC (???)
- ISHNE

Data Submission Process & Data Format Check
ISHNE format,
THEW annotation format,
Clinical Information.

Members/Awarded Users:
- Pharmaceutical/ECG companies
- CROs
- Academic centers
- CSRC (???)

THEW Data Review Group

Application Server
- Data management,
- Access management
- THEW WEB application update

APIs Library

Server for Batch Processing

Database

University of Rochester Medical Center
- HRFUP

FDA-CDER
3/8/2008
The THEW Client application will be distributed to THEW members to visualize, access and process the ECG data from the warehouse.

- **Open APIs for development (summer 2008)**
  - Access to specific ECG dataset
  - Browsing continuous Holter data
  - Selecting ECG interval for client-side processing
  - Access to specific metrics

- **APIs Registration Process (summer 2008)**
  - Configuration of User Interface
  - Analytic DLL
  - Review User Interface

- **Batch Processes for full Holter analysis (2009)**
  - Loading task to URMC server for batch processing of Holter data
  - Generating output to be stored on URMC server
  - Tools for accessing output data
THEW Client Application

Open database

APIs configuration

Membership account information

Logoff from the URMC server

3/8/2008
THEW Client Application
Full ECG Disclosure & APIs access

ECG File ID
Access to the RR tachogram View
Full disclosure View Enabled
Period selection for analysis
- setup:
  Time duration
  Number of leads
APIs Access
Full ECG disclosure

3/8/2008
THEW Client Application
COMPAS QT RR-Bin APIs

ECG File ID

RR bin representation

Cardiac beats visualization tool

Output results
Members

- **Not-for-Profit Organizations**:
  - Universities
  - Scientific and Medical Schools
  - Professional Societies
  - FDA

- **For-profit Organizations**:
  - ECG Equipment Companies
  - Contract Research Organizations
  - Pharmaceutical Companies
  - ECG Core Laboratories
The THEW will generate collaborative research projects:

- Dr. Norman Stockbridge (CDER/FDA)
- Dr. Mark Bocco (Center for Future Health, Rochester, NY)
- International Society for Holter and Non-Invasive Electrocardiology (being submitted)
- Dr. Stefan Kaab (Ludwig-Maximilians-University, Munich, Germany)
- Drs. Pierre Maison-Blanche, Antoine Leenhardt, Fabrice Extramiana (Hospital Lariboisiere, Paris, France)
- Dr. Mark Haigney (Uniformed Services University of the Health Sciences, MD, USA)

- .........................
Structure

Office of Research and Project Administration
Director, Gunta Liders

Office of Regulatory Support
Director, Eric Rubinstein
Clinical and Translational Science Institute

The Telemetric and Holter ECG Warehouse
Cardiology - HRFUP

Office of Counsel
Director, Gail Norris

Office of Technology Transfer
Director, Marjorie Hunter
Medical Center

University of Rochester

3/8/2008
March 2008 –

www.THEWproject.org
QUESTIONS?

Evil speeches destroy good *thews*.

_Wyclif (1 Cor. xv. 33)._
QUESTIONS ?
Evil speeches destroy good *thews*.

*Wyclif (1 Cor. xv. 33).*
Committed Members for year 2008:

**For-Profit Organizations:**

- AMPS, LLC, NY, USA
- GE-Health Care Inc., WI, USA
- Global Instrumentations, LLC, NY, USA
- iCardiac Technologies Inc., NY, USA
- Mortara Instruments, WI, USA
- Philips Medical System, CA, USA
- Schiller America Inc., FL, USA

**Non-For Profit Entities:**

- Dr. Norman Stockbridge (CDER/FDA)
- Center for Future Health (URMC, USA)
- Dr. Kaab (Munich, Germany)
- Dr. Maison-Blanche (Paris, France)
- Dr. Mark Haigney (UHUSH, USA)
- Dr. Marc Bocco (UR, EE school, USA)

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Founding Donation Program

Contact - THEW@heart.rochester.edu
THE THEW WILL FUNCTION UNDER A “COST CENTER” STRUCTURE. THIS STRUCTURE FITS TO NOT-FOR-PROFIT ORGANIZATION REGULATION AND THUS THE FEES REQUIRED TO USERS OF THE WAREHOUSE WILL BE ESTIMATED BASED ON THE EXPENSES TO DEVELOP AND MAINTAIN THE THEW ACTIVITIES. THIS COSTING STRUCTURE WILL BE IN ACCORDANCE WITH OMB CIRCULAR A-21 COSTING FOR SPECIALIZED SERVICE FACILITIES.