



Telemetric *and* Holter ECG Warehouse

URMC/FDA Project for Cardiac Safety Research and Integration of Telemetric/Holter Data to Regulatory Review



The Telemetric and Holter ECG Warehouse (THEW) Project

Concept and Progress

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

Webster's Revised Unabridged Dictionary

Third Mortara Instrument Seminar
February 24-26, Miami, FL

Thew (thew) *n.* (th^ű): Manner; custom; habit; form of behavior; qualities of mind; disposition; specifically, good qualities; virtues

Webster's Revised Unabridged Dictionary

Mission Statement

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.”

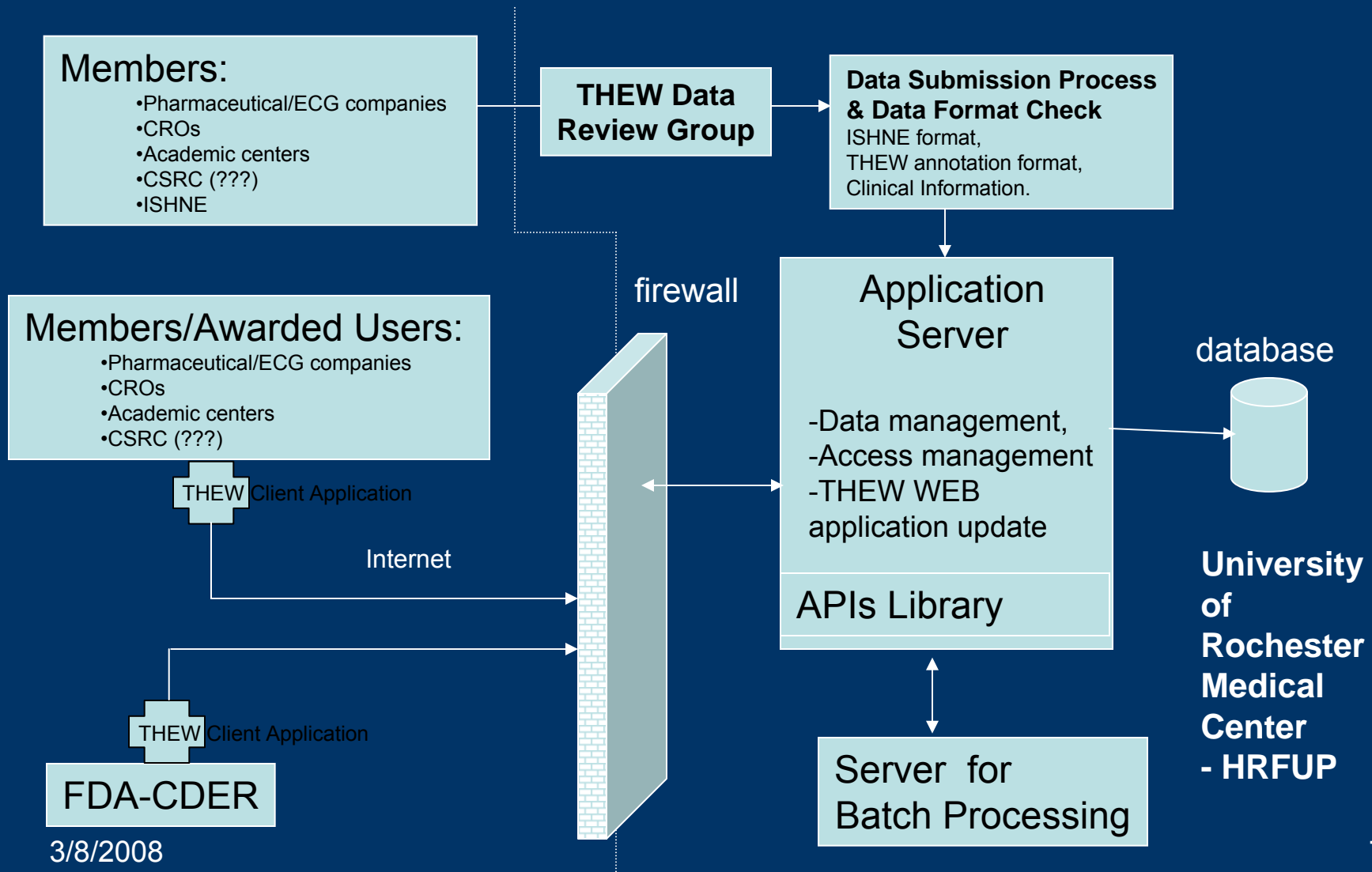
- **Provide Access to Valuable Holter ECG Data for R&D Activities**
 - Cardiac patients (CAD, AMI)
 - Healthy individuals
 - Drug-induced arrhythmias
 - Congenital LQTS
- **Deliver Tools for ECG Data Access and Visualization (THEW Client Application)**
 - Continuous ECG visualization tool
 - Holter annotation 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- URM C ECG metrics
 - Holter annotation full review

Study	ECG type	Contributor	# recordings	Population
IDEAL 1	24-hour Holter	HRFUP	108	Acute Myocardial Infarction
IDEAL 2*	24-hour Holter	HRFUP	265	Healthy Individuals
IDEAL 3	24-hour Holter	HRFUP	294	Coronary Artery Patients
Acqu. LQTS	24-hour Holter	Munich University	3	Drug-induced torsades de pointes
Cong. LQTS 1	24-hour Holter	Munich University	4	Genotyped, torsades de pointes
Sotalol	24-hour Holter	Pfizer Inc.	99	baseline, single and double dose of sotalol (160/320 mg)
Dofetilide	24-hour Holter	Pfizer Inc. ^[1]	5,000	Several drug-induced TdPs and ventricular arrhythmias
Moxifloxacin	24-hour Holter	GSK ^[2]	~100	Thorough QT study
Cong. LQTS 2	24-hour Holter	HRFUP	70	Genotyped

^[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.

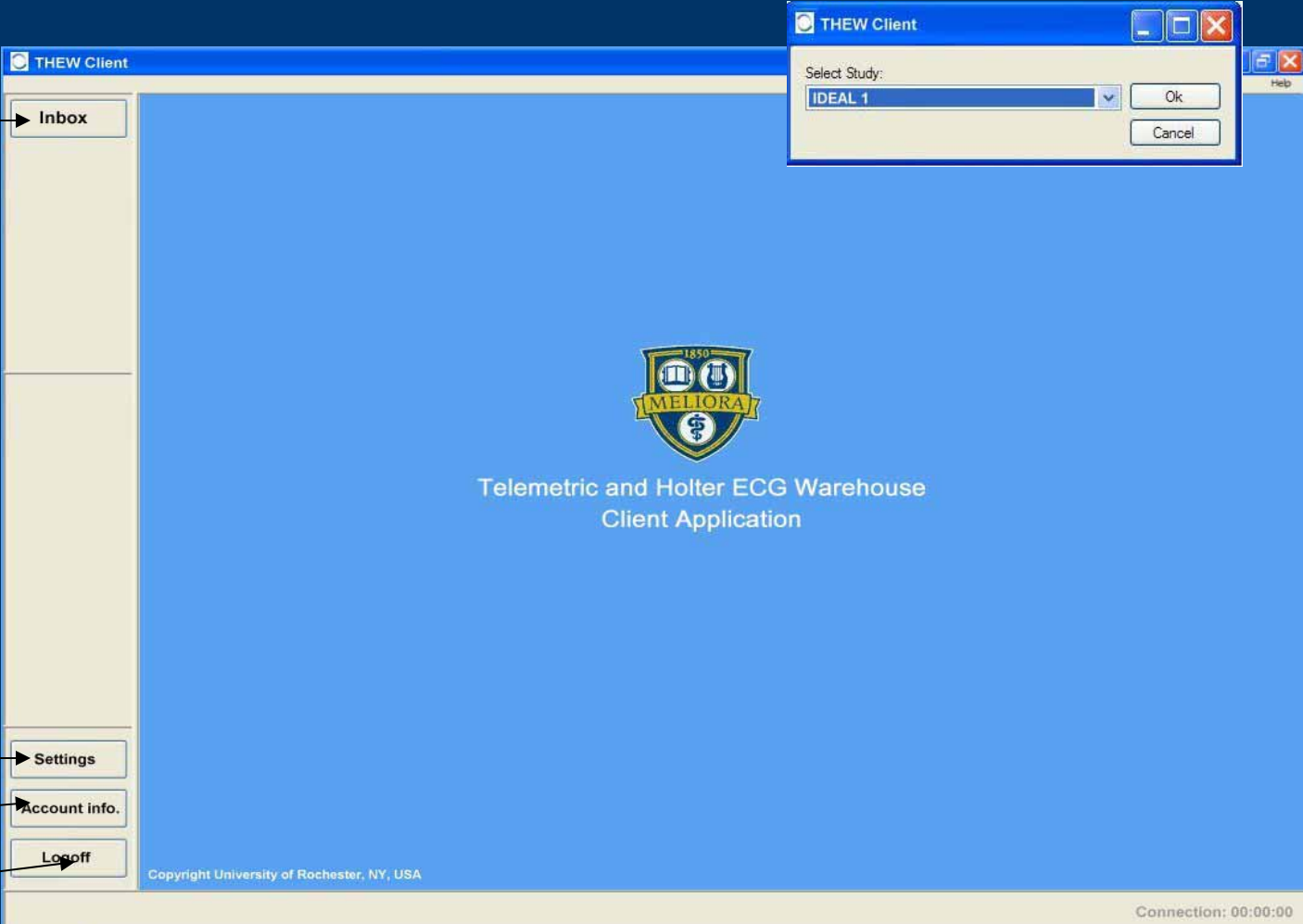
* Data available for the pilot study



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 URMIC server for batch processing of Holter data
 - Generating output to be stored on URMIC sever
 - Tools for accessing output data

THEW Client Application



The screenshot shows the THEW Client application window. On the left is a vertical navigation pane with buttons for 'Inbox', 'Settings', 'Account info.', and 'Logoff'. The main area is blue and contains the University of Rochester logo and the text 'Telemetric and Holter ECG Warehouse Client Application'. A 'Select Study:' dialog box is open, showing 'IDEAL 1' in a dropdown menu and 'Ok' and 'Cancel' buttons. A 'Help' button is visible in the top right corner of the application window. At the bottom right, a status bar shows 'Connection: 00:00:00'. Copyright information for the University of Rochester is at the bottom center.

Open database → Inbox

APIs configuration → Settings

Membership account information → Account info.

Logoff from the URM server → Logoff

Copyright University of Rochester, NY, USA

Connection: 00:00:00

THEW Client Application

Inbox: ECG File Selection

Back to first screen → **Close**

Open ECG File → **Open**

List of available Recordings →

Subject ID	Last Name	First Name	Hook Up Date
IDEAL 1			
STAT613560370			11/27/2007 11:54 AM
m126-01016			11/27/2007 11:45 AM
test			11/27/2007 8:05 AM
test			11/27/2007 8:07 AM
m12R-01018		test	11/26/2007 3:16 PM
M12R-01002_2 43 PM	BTH5nip	BTH5nip	11/26/2007 2:43 PM
m12-1017		test	11/26/2007 2:28 PM
mtt			11/26/2007 2:03 PM
m112-01001		test	11/26/2007 1:02 PM
M12-000125			11/26/2007 12:40 PM
M12-01002			11/26/2007 12:38 PM
M12-529009			11/26/2007 12:36 PM
m12R-52900		test	11/26/2007 12:00 PM
M12R-01002		Test	11/26/2007 11:58 AM
m12R-01025		Test	11/26/2007 11:53 AM
M12R-01001		Test	11/26/2007 11:50 AM
M12-01017		Test	11/26/2007 11:49 AM
M12-01018		Test	11/26/2007 11:45 AM
m12-01018		tuesday	11/26/2007 10:09 AM
m12R-01017			11/24/2007 10:17 AM
m12R-01018			11/24/2007 10:16 AM
1234			11/15/2007 6:31 PM
STAT331782904			11/14/2007 2:17 PM
STAT495204148			11/14/2007 12:31 PM
M12R-01016	Test	Wed	11/14/2007 9:21 AM
wa05			11/13/2007 2:12 PM
phatom			11/13/2007 2:07 PM
PH 3			11/13/2007 1:55 PM
PH two			11/13/2007 1:49 PM
12345	one	test	11/13/2007 12:55 PM
PH			11/13/2007 12:37 PM
12-lead subject			11/13/2007 12:30 PM
M12R-01016	thousand	Twelve	11/13/2007 12:09 PM
M12R-01016	test	Test	11/13/2007 11:19 AM
STAT217039018	STATdtp	STATdtp	9/25/2007 12:38 PM
60 BPM 18 hours	Test	Recording	8/12/2007 3:57 PM
Changes 12 Lead	Test	Recording	8/12/2007 1:38 PM
ST - 2	Test	Recording	8/12/2007 1:22 PM
Ventricular Run	Test	Recording	8/12/2007 12:50 PM

Logging off from URM server → **Logoff**

Connection: 01:23:12

THEW Client Application

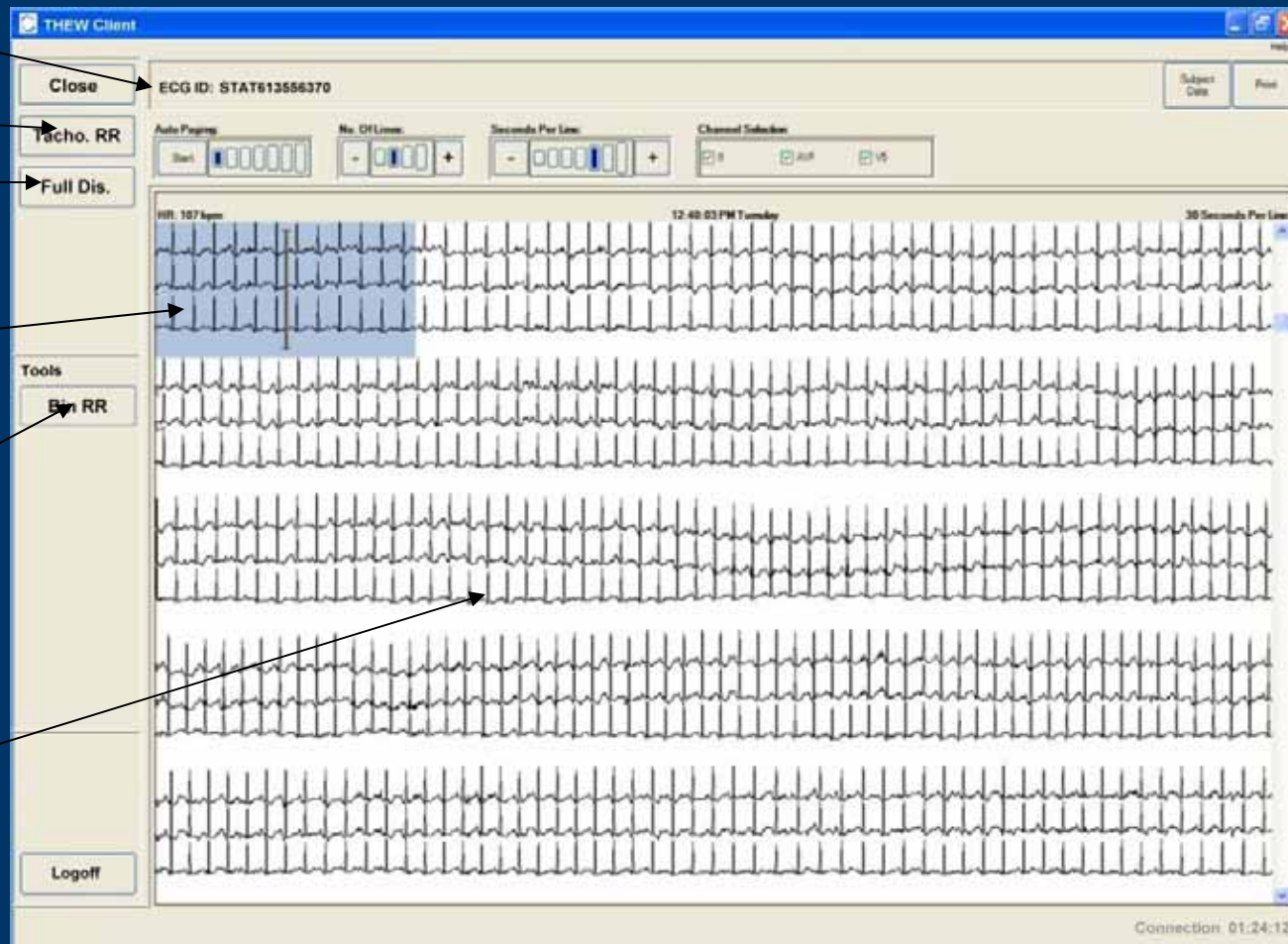
Full ECG Disclosure & APIs access

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



THEW Client Application

RR Tachogram tool & APIs access

The screenshot displays the THEW Client application interface. At the top, the window title is 'THEW Client' and the ECG ID is 'STAT613556370'. The interface includes a 'Close' button, 'Tacho. RR' and 'Full Dis.' buttons, and a 'Tools' section with a 'Bin RR' button. The main display area is divided into two sections: the top section shows an RR Tachogram plot with a y-axis from 0 to 2000 and an x-axis from 11:00 to 1:00; the bottom section shows an ECG strip with a heart rate of 63 bpm and a timestamp of 1:07:31 PM Tuesday. The ECG strip includes numerical values (726, 691, 868, 1149, 1095, 1137, 1090) and 'N' markers above the waveforms. A 'Logoff' button is located at the bottom left. The connection time '01:24:12' is shown at the bottom right.

ECG File ID

RR tachogram View enabled

Access to Full disclosure View

RR Tachogram

APIs Access

ECG strip

THEW Client Application

COMPAS QT RR-Bin APIs

ECG File ID



RR bin representation

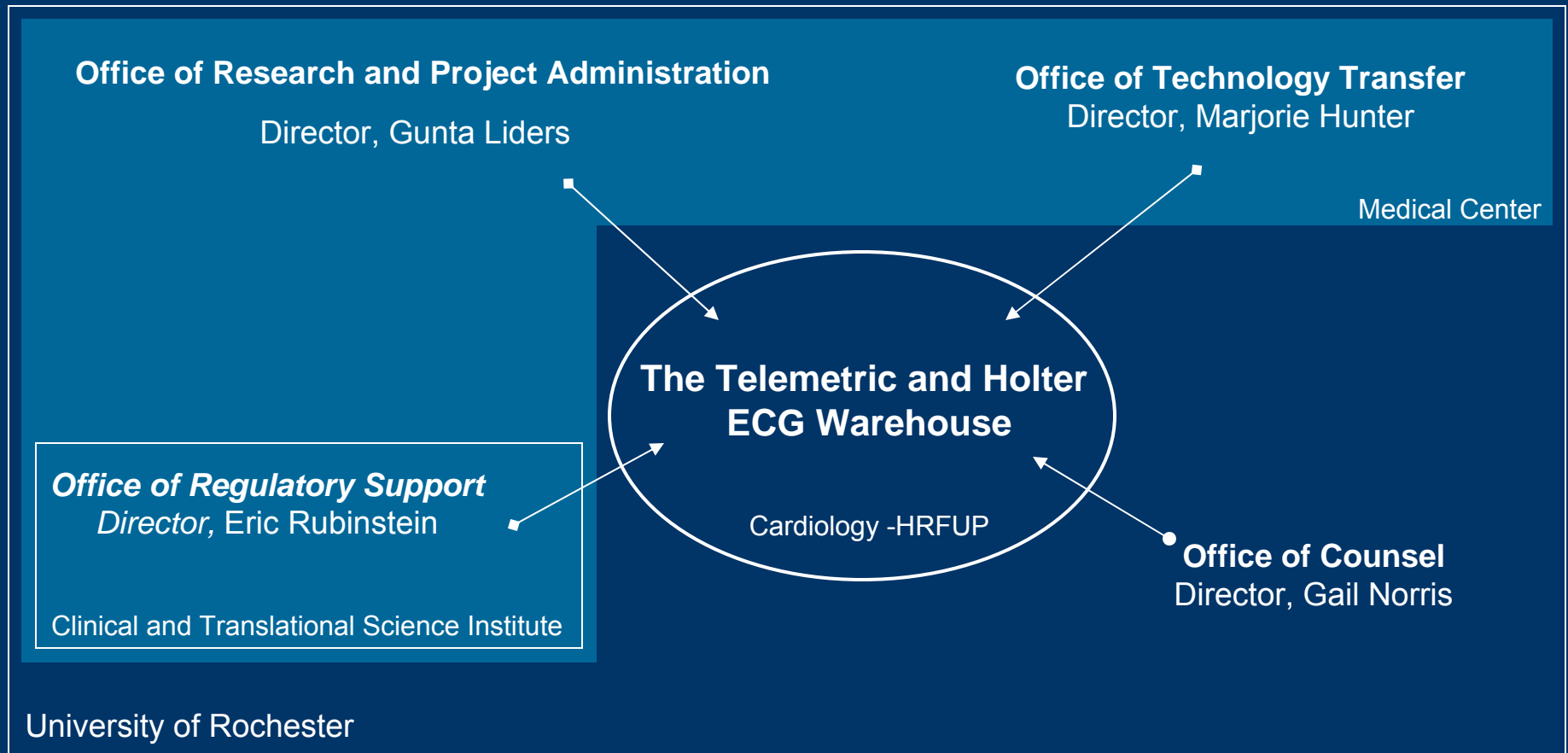
Cardiac beats visualization tool

Output results

- **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:

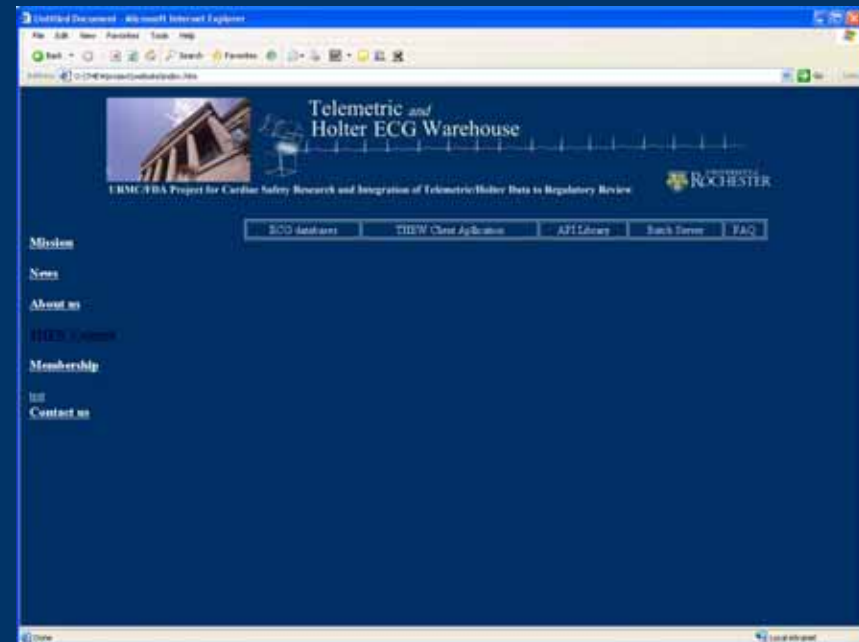
- **Dr. Norman Stockbridge (CDER/FDA)**
- **Dr. Mark Bocco (Center for Future Health, Rochester, NY)**
- **International Society for Holter and Non-Invasive Electrocardiology (being submitted)**
- **Dr. Stefan Kaab (Ludwig-Maximilians-University, Munich, Germany)**
- **Drs. Pierre Maison-Blanche , Antoine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



March 2008 –



March 2008 –



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)

.....

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.