



# 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<sup>u</sup>): 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.”

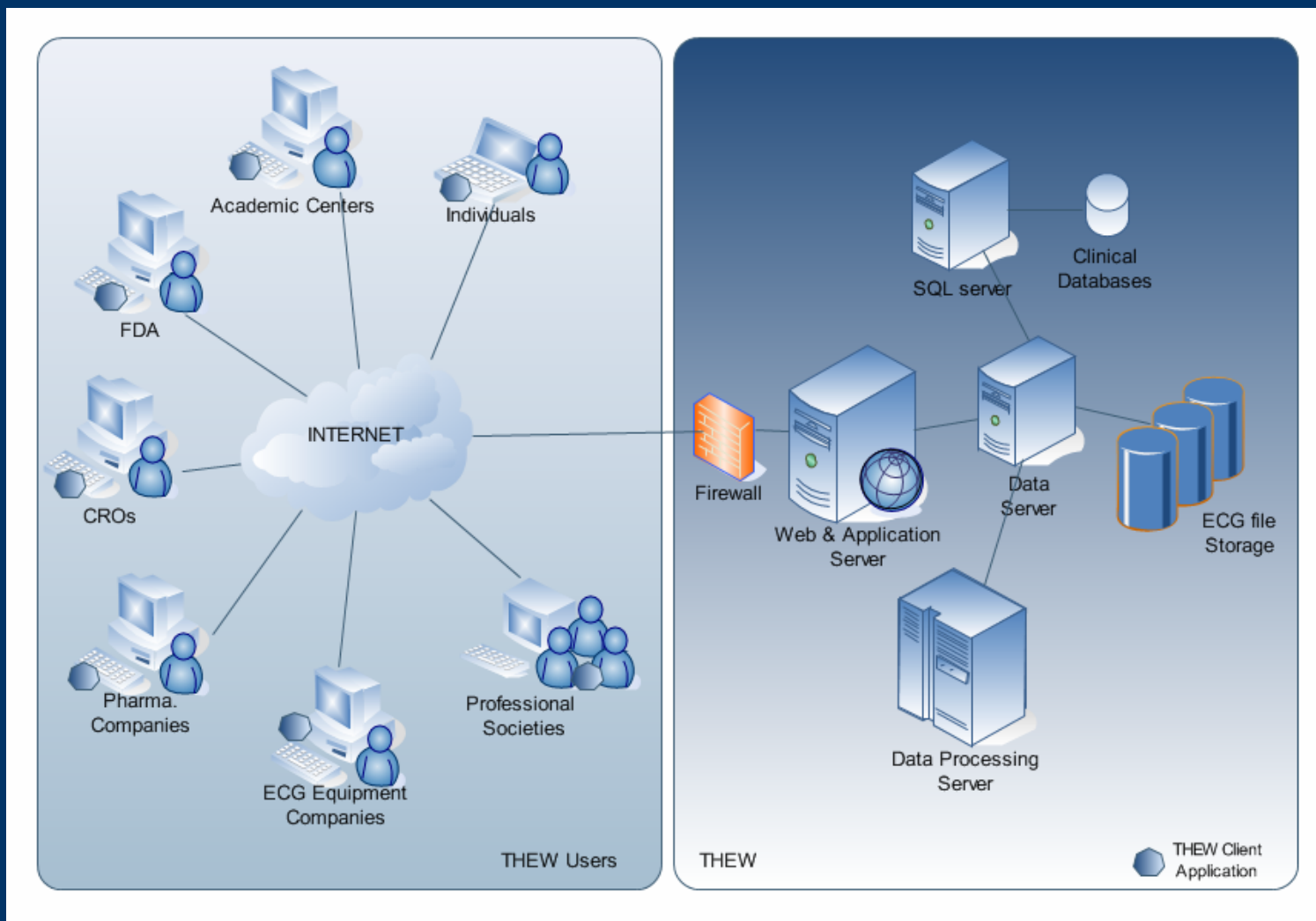
- **Provide Access to Valuable Holter ECG Data for R&D Activities**
  - Cardiac patients (CAD, AMI)
  - Healthy individuals
  - Drug-induced arrhythmias
  - Congenital LQTS
- **Deliver Tools for ECG Data Access and Visualization (THEW Client Application)**
  - Continuous ECG visualization tool
  - Holter annotation information
- **Open Tools for the Development of Application Programming Interfaces (APIs) compatible with the THEW Client Application**
- **Share technologies using an API Library**
- **Batch Server features (based on available computer resources)**
- **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. <sup>[1]</sup>	5,000	Several drug-induced TdPs and ventricular arrhythmias
Moxifloxacin	24-hour Holter	GSK <sup>[1]</sup>	~100	Thorough QT study
Cong. LQTS 2	24-hour Holter	HRFUP	70	Genotyped

<sup>[1]</sup> Sharing of the data for THEW is being discussed.

\* Data available for the pilot study

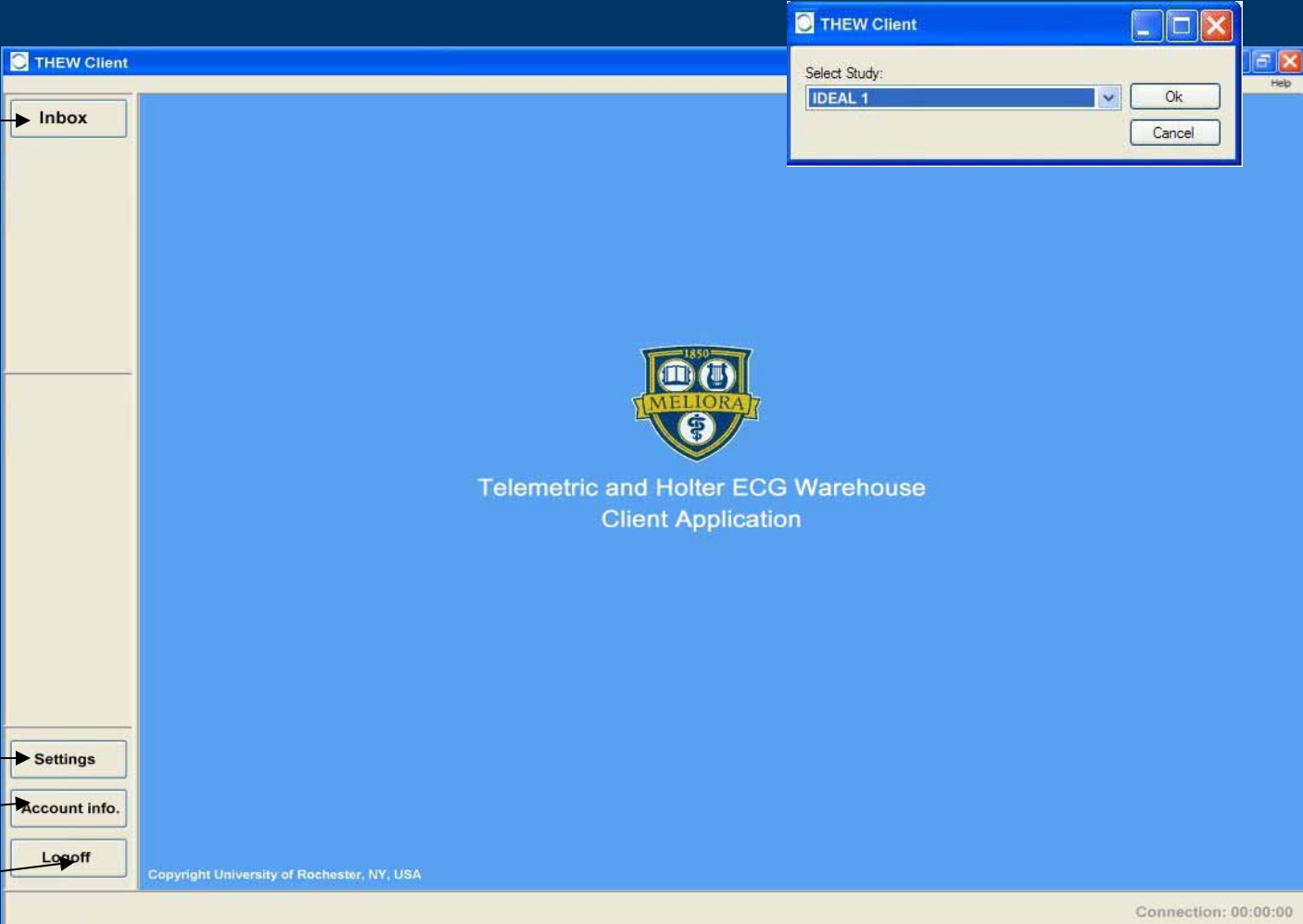
# Architecture



**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 text 'Copyright University of Rochester, NY, USA' is at the bottom center.

Open database → Inbox

APIs configuration → Settings

Membership account information → Account info.

Logoff from the URMC server → Logoff

Connection: 00:00:00

3/11/2008

# THEW Client Application

Full ECG Disclosure & APIs access

ECG File ID  
Access to the RR tachogram View

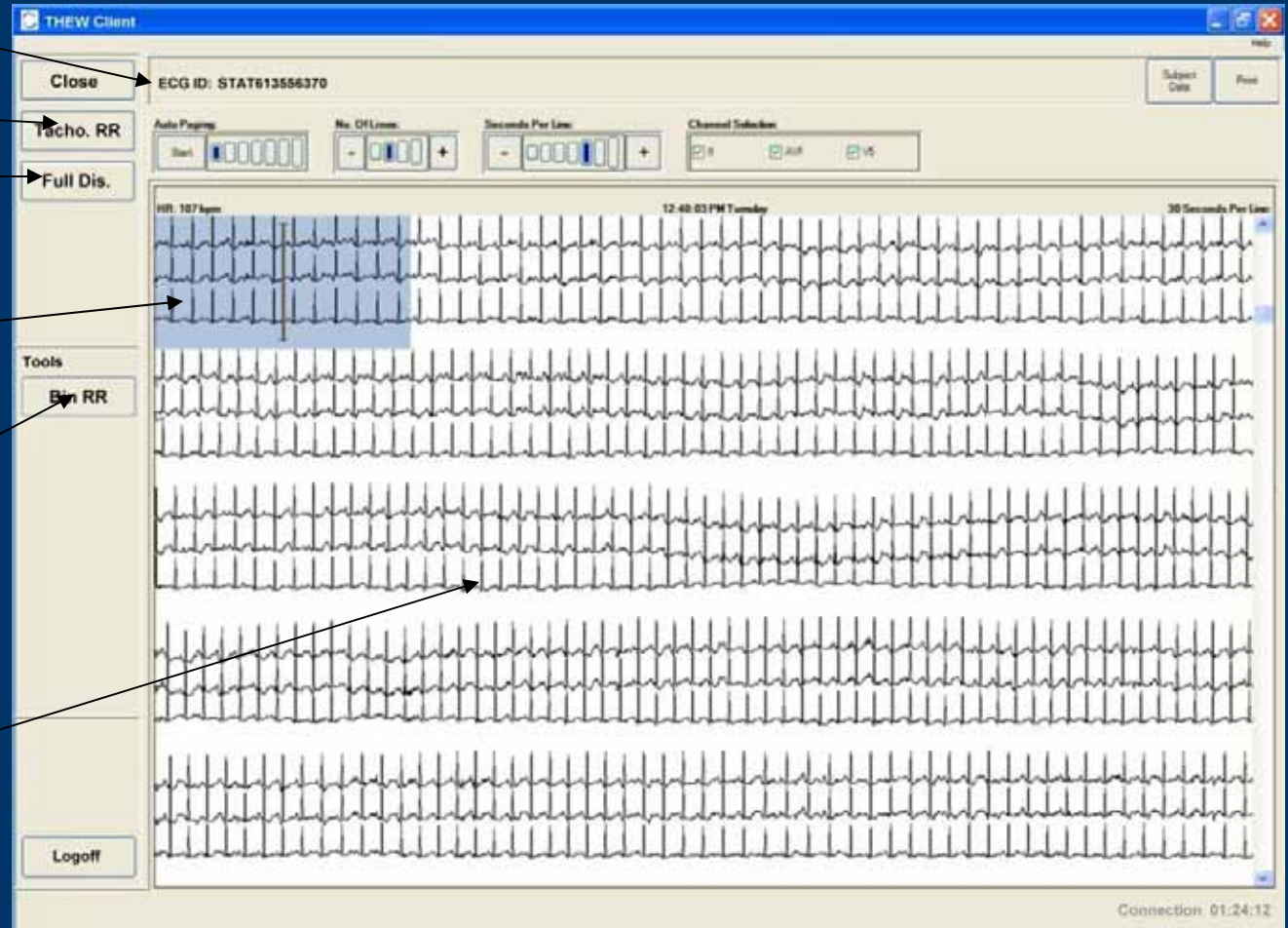
Full disclosure View Enabled

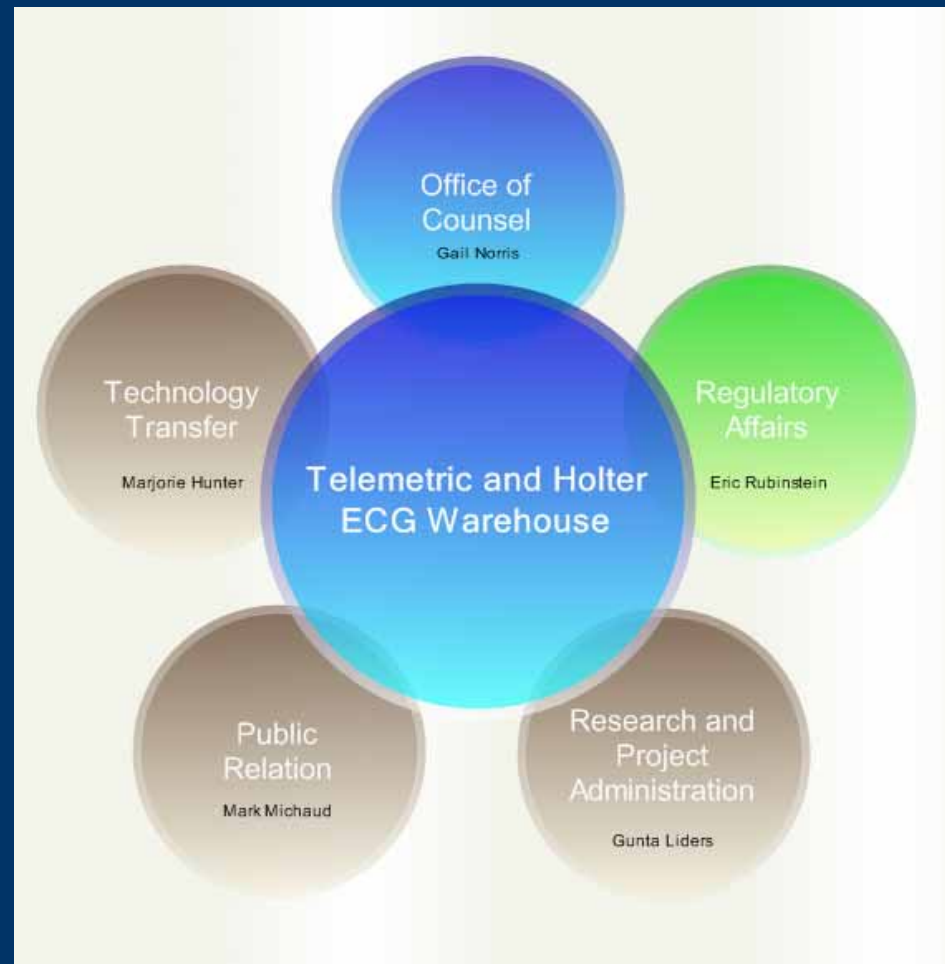
Period selection for analysis  
-setup:

Time duration  
Number of leads

APIs Access

Full ECG disclosure





March 2008

Release of the THEW website



3/11/2008