UNIVERSITY *of* ROCHESTER

The TELEMETRIC *and* HOLTER ECG WAREHOUSE *Project*

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

The TELEMETRIC and HOLTER ECG WAREHOUSE Project

Agenda

13:00-13:10	**Introductory Comments –** N Stockbridge
13:10-14:00	**The Telemetric and Holter Warehouse Project -** JP Couderc
14:00-15:15	**Interest of using Holter Technologies in Cardiac Safety Studies** Justin Mortara (Mortara Instrument) Fabio Badilini (AMPS LLC) Marek Malik (on behalf of GE Health Care Inc.) Anthony Fossa (Pfizer Inc.) Mikael Totterman (iCardiac Technologies Inc.)
15:15-15:30	**Break**
15:30-15:45	**CSRC : Involvement and Update -** P Kligfield
15:45-16:00	**FDA Perspectives -** N Stockbridge
16:00-17:00	**Discussion**

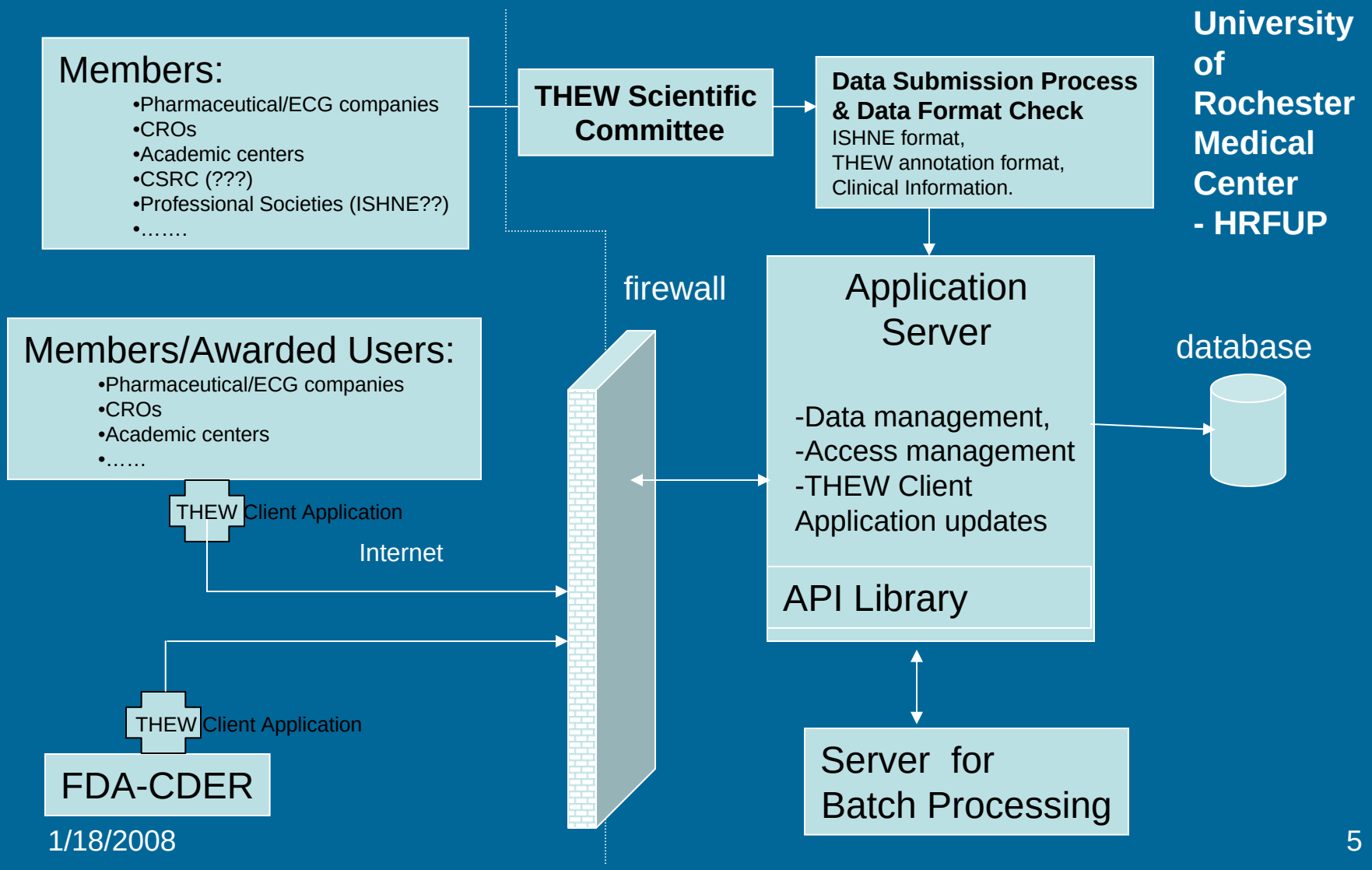
Mission Statement

The objective of the *Telemetric and Holter ECG Warehouse (THEW)* is to provide access to continuous electrocardiographic data to for-profit and non-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.

Deliverables

- **ECG data for R&D activities**
  - Cardiac patients
  - Healthy individuals
  - Drug–induced arrhythmias
  - Congenital LQTS
- **Tools for ECG data access and visualization (THEW Client Application)**
  - Continuous ECG visualization tool
  - Holter annotation information
- **Tools for the development of Application Programming Interfaces (APIs) compatible with the THEW Client Application**
- **API Library**
- **Access to ECG metrics**
  - HRFUP- URMC ECG metrics
  - Holter annotation full review

Architecture



THEW Content

	Study	ECG type	Contributor	# recordings	Population
Summer 2008	**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
2008	**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. [1]	99	baseline, single and double dose of sotalol (160/320 mg)
2009	**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.

THEW Client Application

The THEW Client application will be distributed to THEW members* to visualize, access and process the ECG data from the warehouse.

- ✓ **Summer 2008:**
  - **THEW Client Application**
    - Access to database
    - Browsing and selection of ECG files
    - Review of continuous Holter Signal
    - Access to ECG signal from selected periods for client-side processing
    - Access to ECG metrics
  - **Application Programming Interfaces (APIs)**
    - White paper describing API registration process
    - System Development Kit (SDK)
    - Example of basic APIs code

(* Depending on their membership level)

THEW Client Application

The THEW Client application will be used to run batch processing on continuous Holter Data and to develop and distribute APIs compatible with the THEW client application.

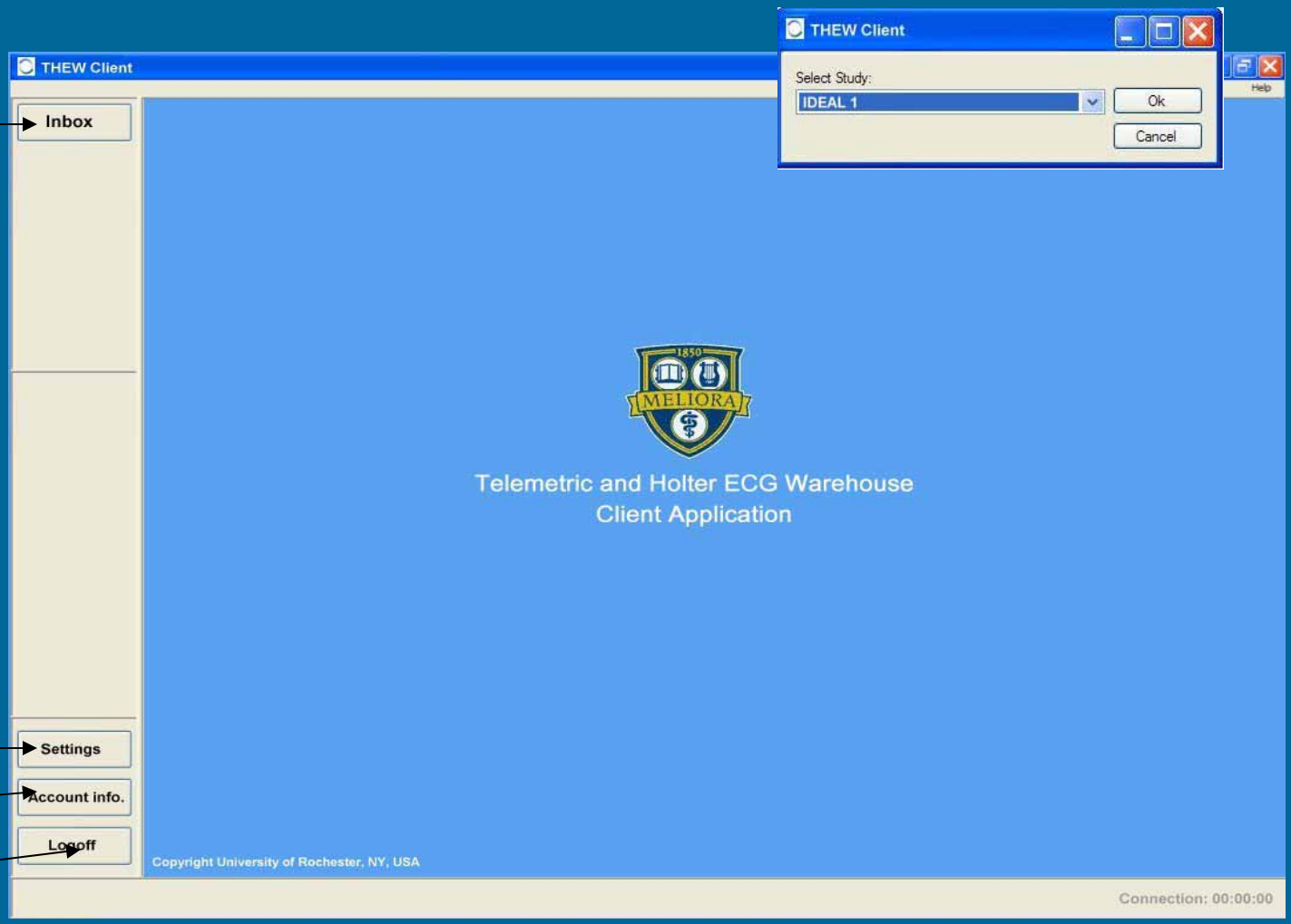
✓ **Summer 2009:**

- **Batch Processes for full Holter analysis**
  - Loading task to URMC server for batch processing of Holter data
  - Generating output to be stored on URMC sever
  - Tools for accessing output data

- **API Library**
  - API management system
  - Upload and download features

THEW Client Application

Login



Open database

APIs configuration

Membership account information

Logoff from the URMC server

THEW Client Application

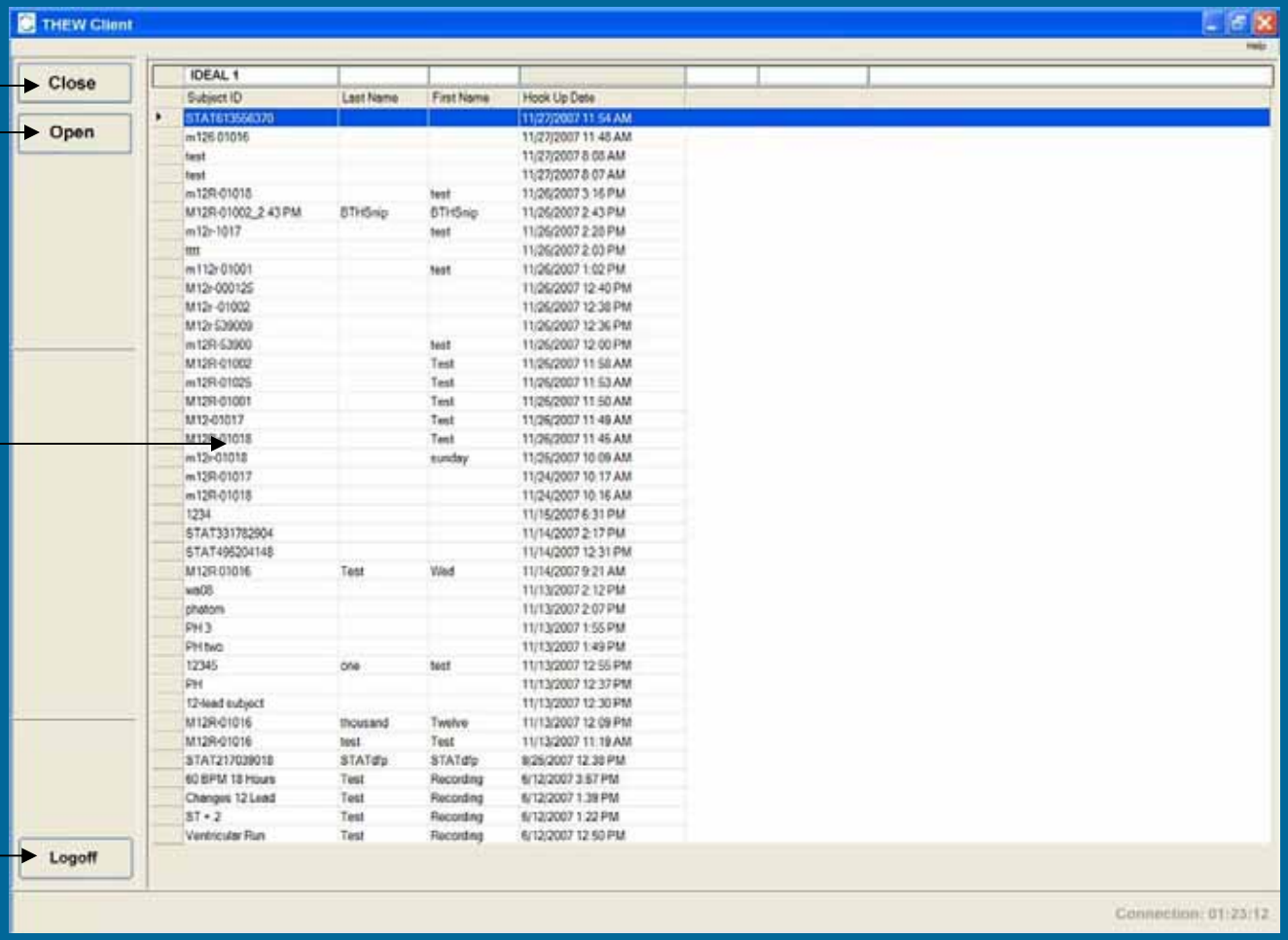
Inbox: ECG File Selection

Back to first screen

Open ECG File

List of available Recordings

Logging off from URMC server



THEW Client Application

Full ECG Disclosure & APIs access

ECG File ID

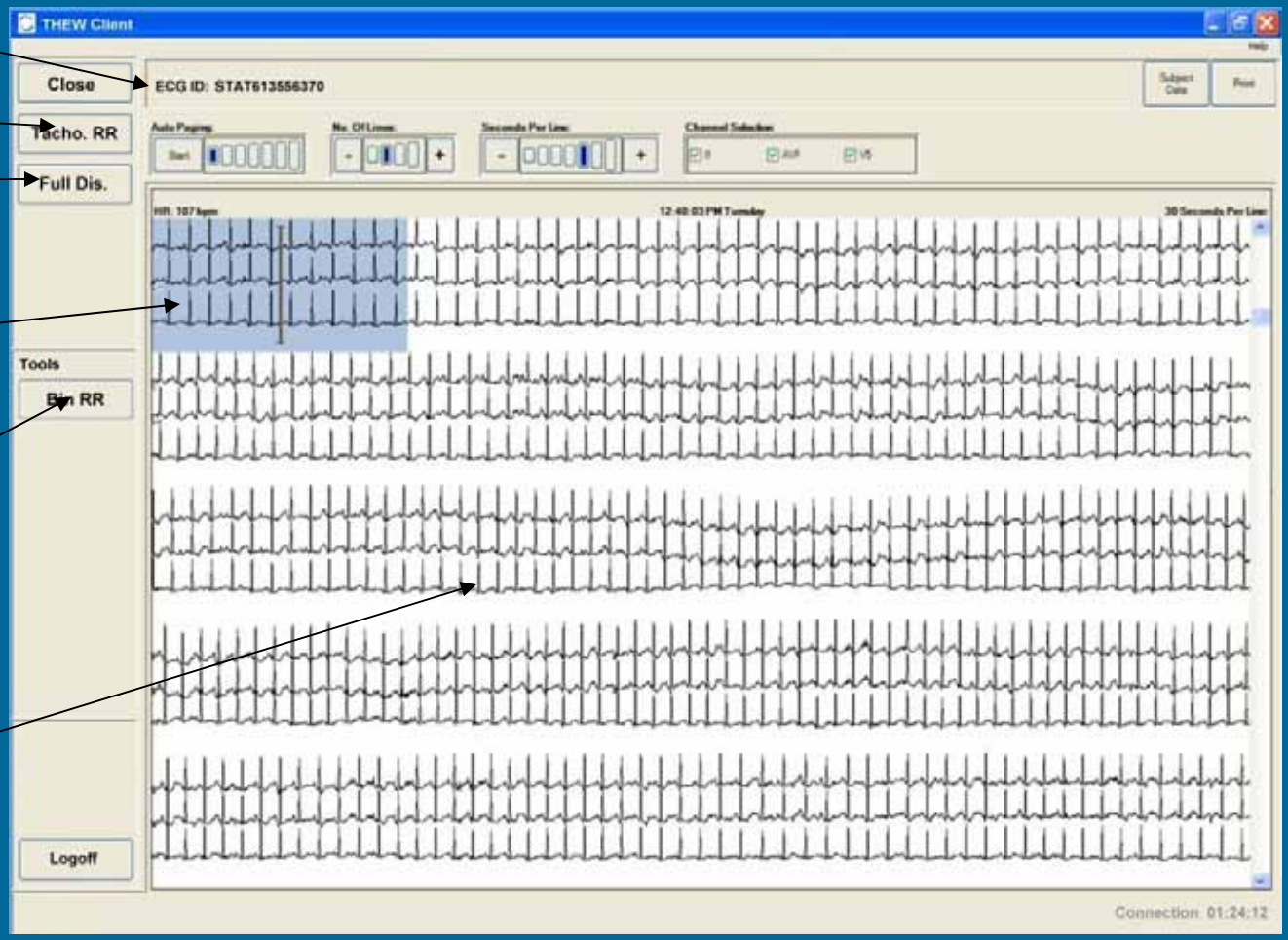
Access to the RR tachogram View

Full disclosure View Enabled

Period selection for analysis
-setup:
Time duration
Number of leads

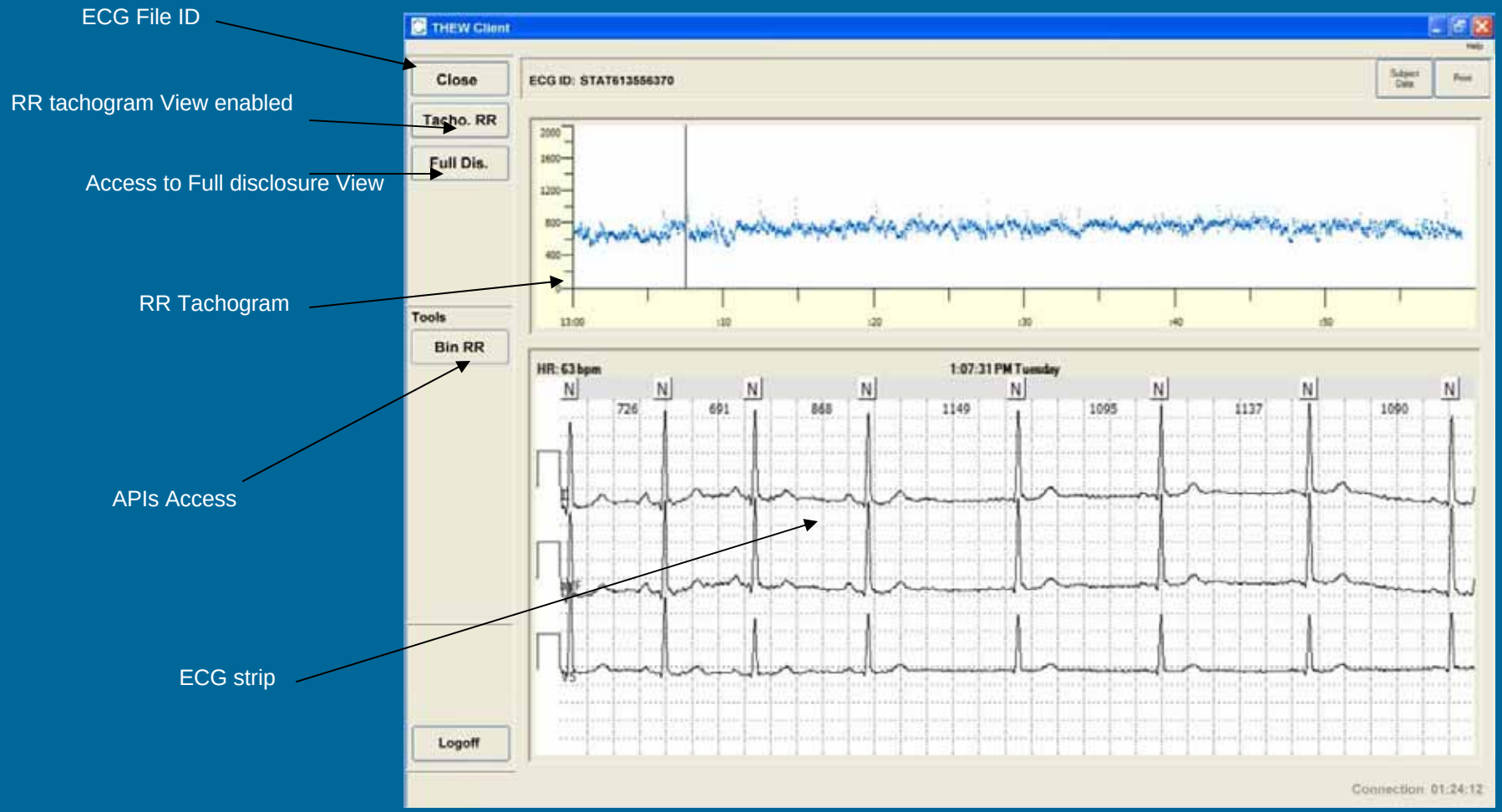
APIs Access

Full ECG disclosure



THEW Client Application

RR Tachogram tool & APIs access



THEW Client Application

COMPAS QT RR-Bin APIs

ECG File ID

RR bin representation

Cardiac beats visualization tool

Output results

Expected Members

- **Non-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

THEW Members

committed 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**

THEW Members

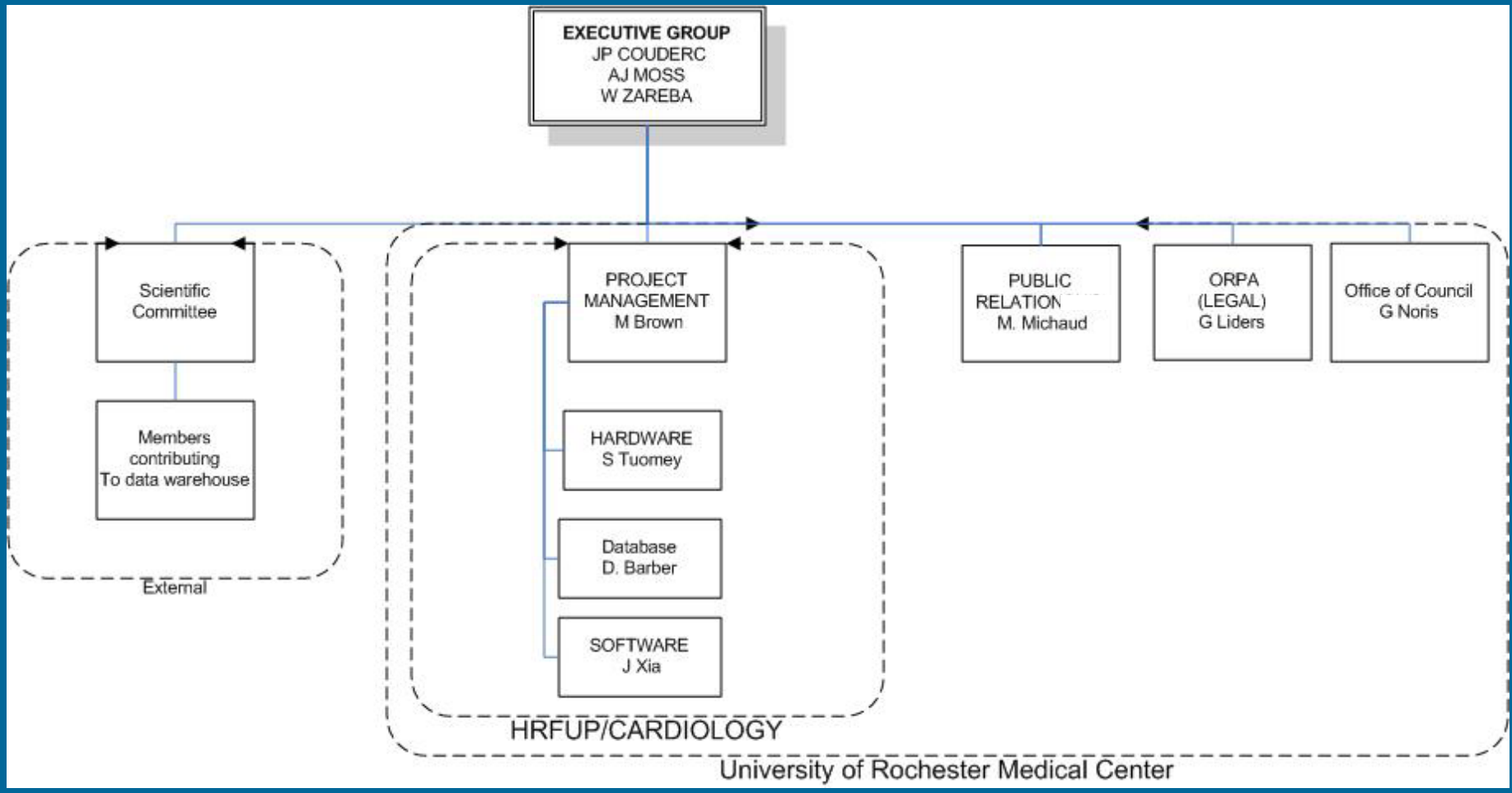
committed for year 2008

Non-For Profit Entities:

- **Dr. Norman Stockbridge (CDER/FDA)**
- **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)**

…….

The THEW Team



Conclusion

The THEW will provide access to valuable scientific data in order to facilitate the development of ECG technologies for cardiac safety.

Presentations

The objective of the Session is to provide descriptions of scientific work supporting the use of Holter Technologies in drug safety studies.

Cardiac Research Safety Consortium

Paul Kligfield, MD

FDA perspectives

Norman Stockbridge, FDA -CDER