



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**



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.



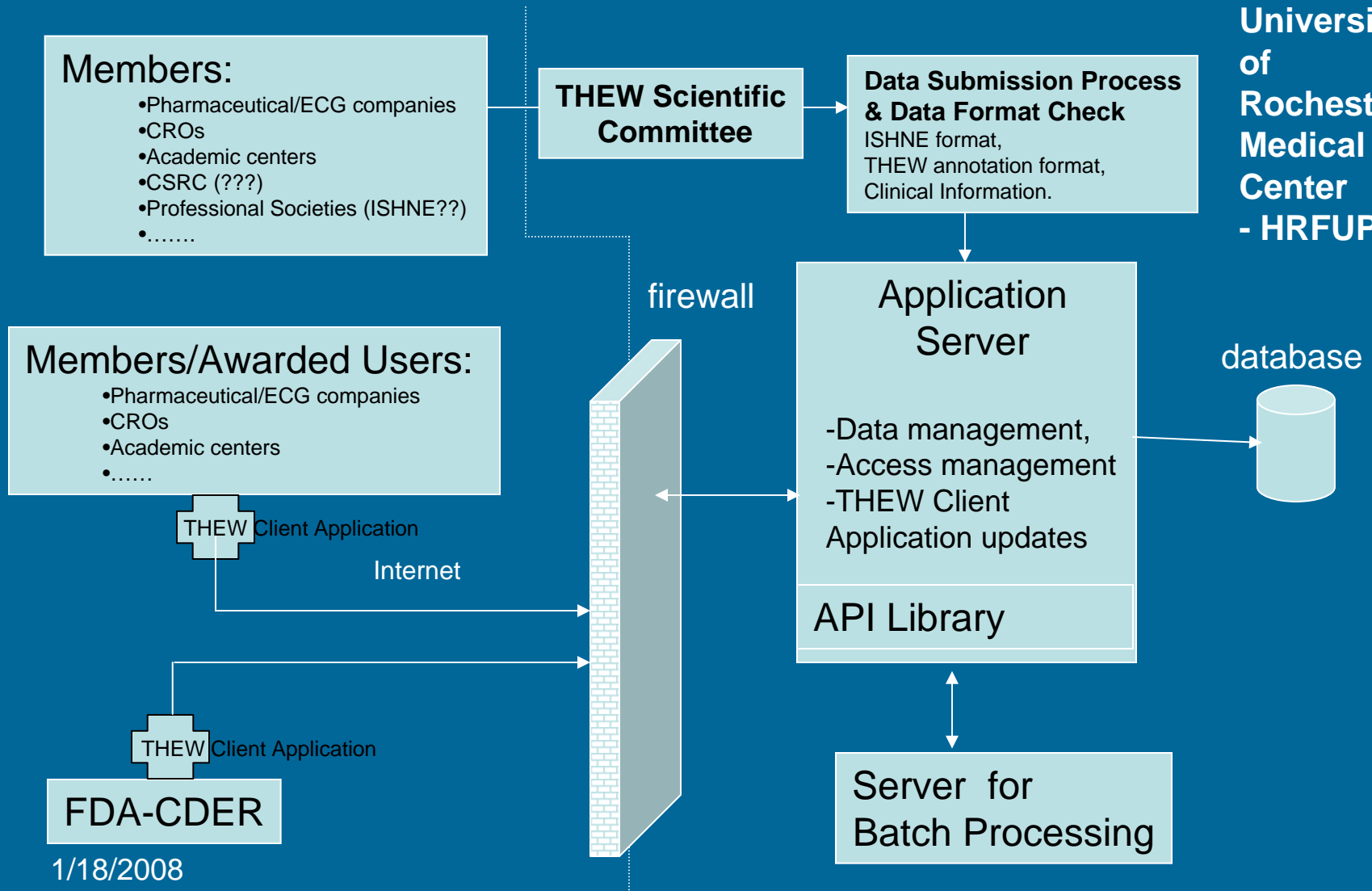
Deliverables

- **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- URM C ECG metrics
 - Holter annotation full review



Architecture

University
of
Rochester
Medical
Center
- HRFUP



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



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

The screenshot shows the THEW Client application interface. The main window has a blue header with the title 'THEW Client'. Below the header is a navigation pane on the left with buttons for 'Inbox', 'Settings', 'Account info.', and 'Logoff'. The main content area is blue and features the University of Rochester logo (a shield with '1850' at the top, 'MELIORA' on a banner, and a caduceus at the bottom) and the text 'Telemetric and Holter ECG Warehouse Client Application'. A small dialog box titled 'THEW Client' is open in the top right, showing a 'Select Study:' dropdown menu with 'IDEAL 1' selected, and 'Ok' and 'Cancel' buttons. A 'Help' button is visible in the top right corner of the main window. At the bottom right of the main window, it says 'Connection: 00:00:00'. At the bottom left of the main window, it says 'Copyright University of Rochester, NY, USA'.

Open database → Inbox

APIs configuration → Settings

Membership account information → Account info.

Logoff from the URM server → Logoff

THEW Client

Select Study:
IDEAL 1

Ok
Cancel

Help

1850
MELIORA

Telemetric and Holter ECG Warehouse
Client Application

Connection: 00:00:00

Copyright University of Rochester, NY, USA

1/18/2008

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
photon			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

The screenshot displays the THEW Client application interface. At the top, the window title is 'THEW Client'. Below the title bar, there is a 'Close' button and the text 'ECG ID: STAT613556370'. To the right of this are 'Subject Data' and 'Print' buttons. Below the ECG ID, there are three control sections: 'Auto Pacing' with a 'Start' button and a progress bar, 'No. Off Lines' with a minus sign, a progress bar, and a plus sign, and 'Seconds Per Line' with a minus sign, a progress bar, and a plus sign. To the right of these is a 'Channel Selection' section with three checkboxes labeled 'I', 'aVF', and 'V5'. Below these controls is the main ECG display area. It shows a heart rate of 'HR: 107 bpm' and a timestamp of '12:40:03 PM Tuesday'. The ECG traces are arranged in a grid. A blue shaded region highlights a portion of the top trace. Below the ECG display is a 'Tools' section with a 'Bin RR' button. At the bottom left is a 'Logoff' button. At the bottom right, the text 'Connection: 01:24:12' is visible. Several arrows point from text labels on the left to specific elements in the interface: 'ECG File ID' points to the ECG ID text; 'Access to the RR tachogram View' points to the 'Bin RR' button; 'Full disclosure View Enabled' points to the 'Full Dis.' button; 'Period selection for analysis -setup:' points to the blue shaded region on the ECG trace, with sub-labels 'Time duration' and 'Number of leads' pointing to the width and height of the selection respectively; 'APIs Access' points to the 'Bin RR' button; and 'Full ECG disclosure' points to the main ECG display area.

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. The window title is "THEW Client". The main area is divided into two sections. The top section shows an RR Tachogram plot with a y-axis ranging from 0 to 2000 and an x-axis showing time from 11:00 to 11:30. The plot shows a dense blue line representing RR intervals. 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 displays multiple leads with R-peaks labeled with values: 726, 691, 868, 1149, 1095, 1137, and 1090. The interface includes a sidebar with buttons: "Close", "Tacho. RR", "Full Dis.", "Tools", and "Bin RR". A "Logoff" button is located at the bottom left. The status bar at the bottom right shows "Connection 01:24:12".

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



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**



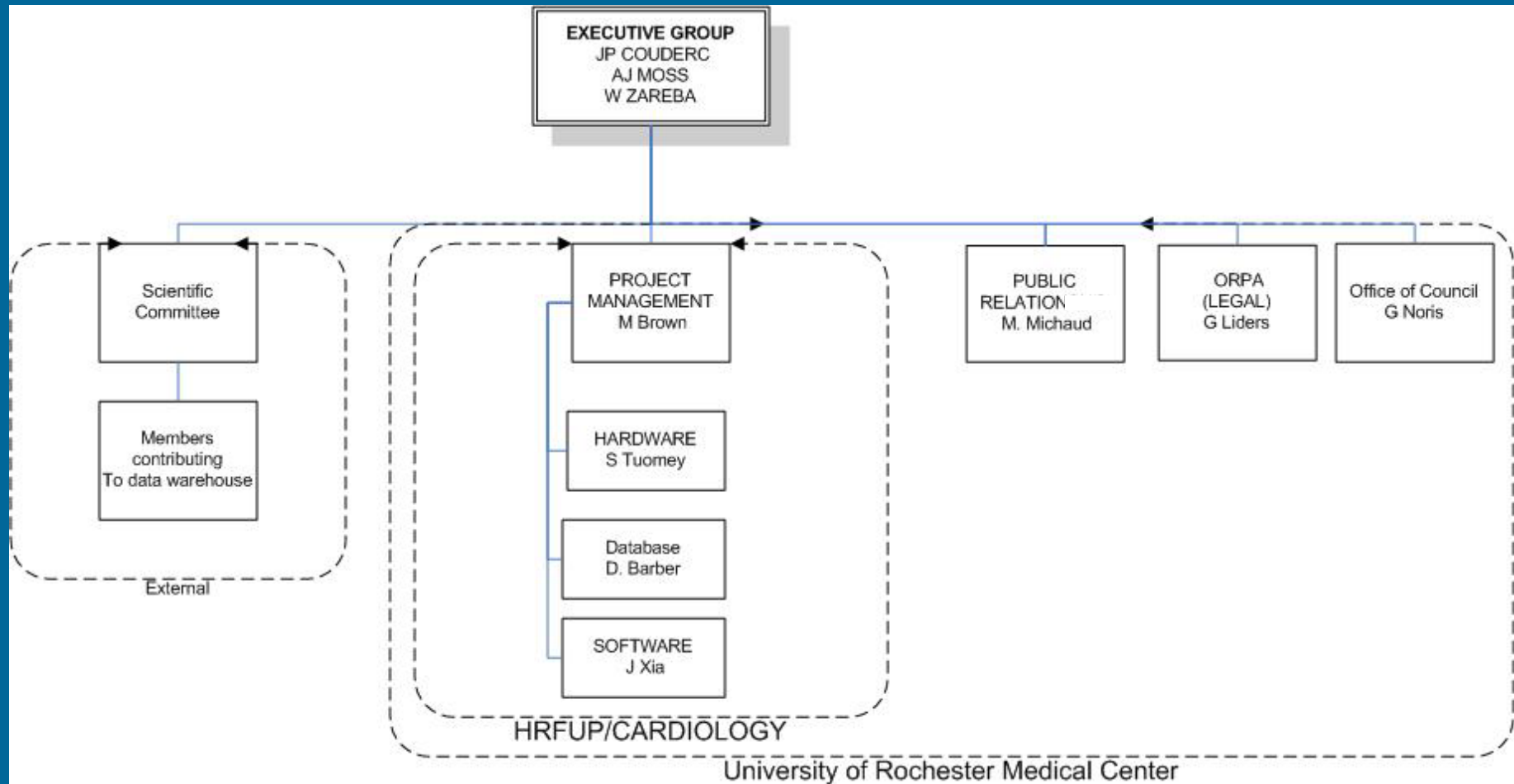
THEW Members

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