

# The Telemetric and Holter ECG Warehouse (THEW) Initiative

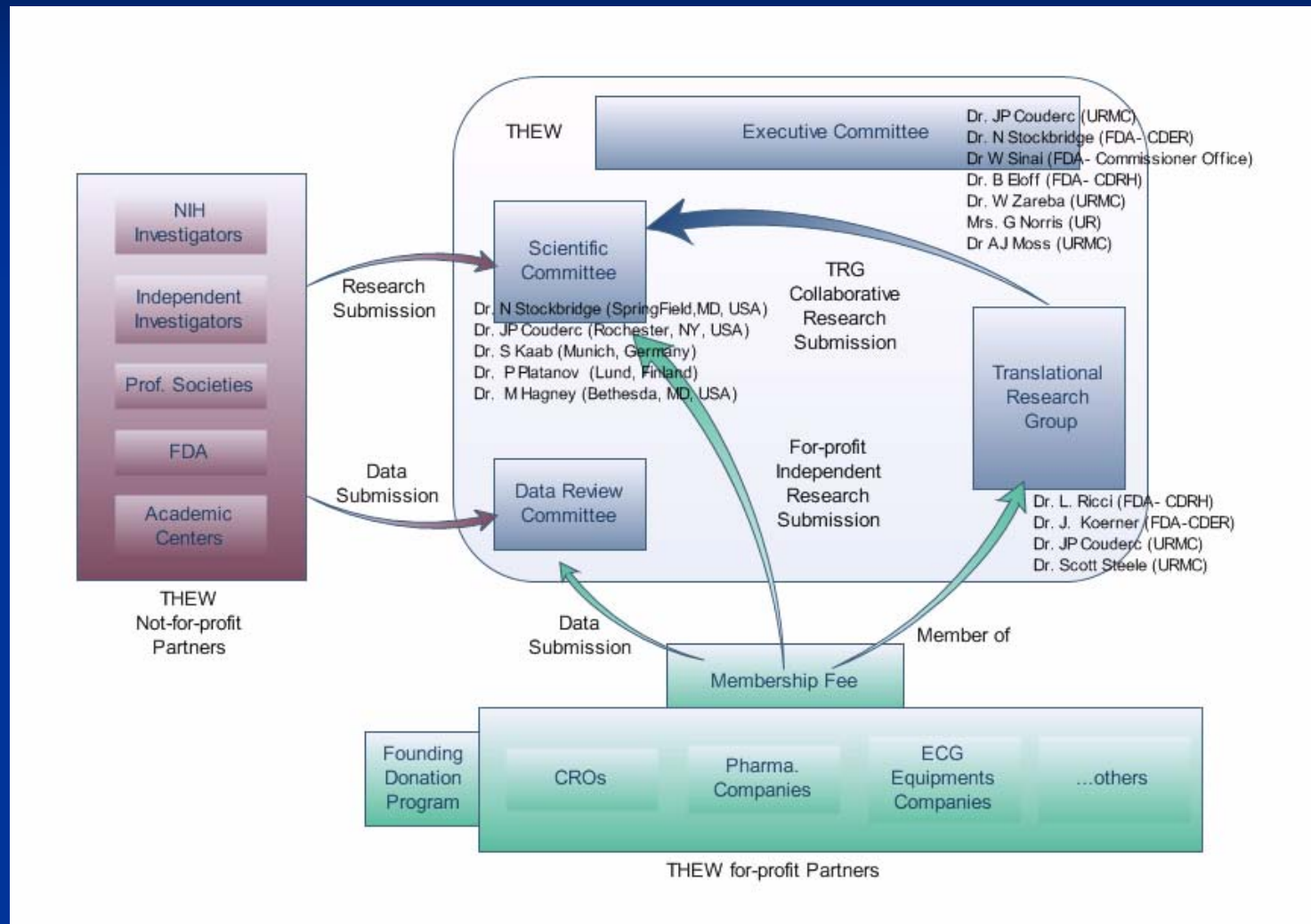
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THEW – HRFUP- Cardiology  
University of Rochester Medical Center, NY



# Mission Statement

The objective of the *Telemetric and Holter ECG Warehouse (THEW)* is to provide access to 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.

# Governance



# FDA- THEW Agreement

**UNIVERSITY of ROCHESTER**  
TELEMETRIC and HOLTER ECG Warehouse

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## SECOND THEW EVENT HOSTED AND SPONSORED BY THE FDA

**FDA U.S. Food and Drug Administration**  
Protecting and Promoting Your Health

APRIL 29TH, 2009 - FDA HEADQUARTER, SILVER SPRING, MD

The second THEW meeting is scheduled for April, 29th at the FDA headquarter (White Oak Campus) in Silver Spring (MD). This is a FREE event during which most recent updates about our initiative will be presented. The THEW meetings are opportunities to meet regulators and discuss current issues related to cardiac safety. The deadline for registration is Tuesday April 21st, 2009. Please click on the link below to register and find more information about this event. The topics discussed during the meeting will include:

- 1 Update about the Telemetric and Holter ECG Warehouse (THEW)
- 2 Drug Safety and Cardiac Issues: Evaluation of drug modifying the autonomic regulation of the heart, Computerized QT Technologies in drug safety trial; Rate correction and hysteresis of the QT interval
- 3 Beyond QT prolongation: T-wave alternans, repolarization instability and T-wave morphology
- 4 Drug safety and computer ECG modeling
- 5 Continuous ECG in drug safety studies - FDA perspectives

[Download the Brochure in PDF](#) and [Click Here to Register](#)

About the THEW: On January 15th, 2009, the THEW was open and fully operational: ECG signals and their associated clinical information can be accessed from our server hosted at the University of Rochester Medical Center, NY. The Warehouse has received several databases from which millions of 12-lead standard ECG recordings and hundreds of Holter recordings can be downloaded. This data has been shared by pharmaceutical companies and research organization from all over the world.

### THEW IN THE NEWS

[03/28/2009] Public and Private partnership to help determine Clinical Biomarker Utility in Applied Clinical Trials online.com >[here](#)

[03/16/2009] eClinica.com >[here](#)

[01/13/2009] Medical News Today .com >[here](#)

[01/12/2009] Forbes.com >[here](#)

[07/09/2008] Applied Clinical Trials Online.com >[here](#)

### RECENT UPDATES

[11/01/2008] Striving to advance the field of cardiac safety, the THEW initiative is developed for facilitating collaborative discussions between THEW members, and for leveraging resources to implement joint projects among FDA, University of Rochester (UR), and other public and private stakeholders. The THEW is led by individuals from the UR, the Commissioner Office of the FDA, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health. [More...](#)

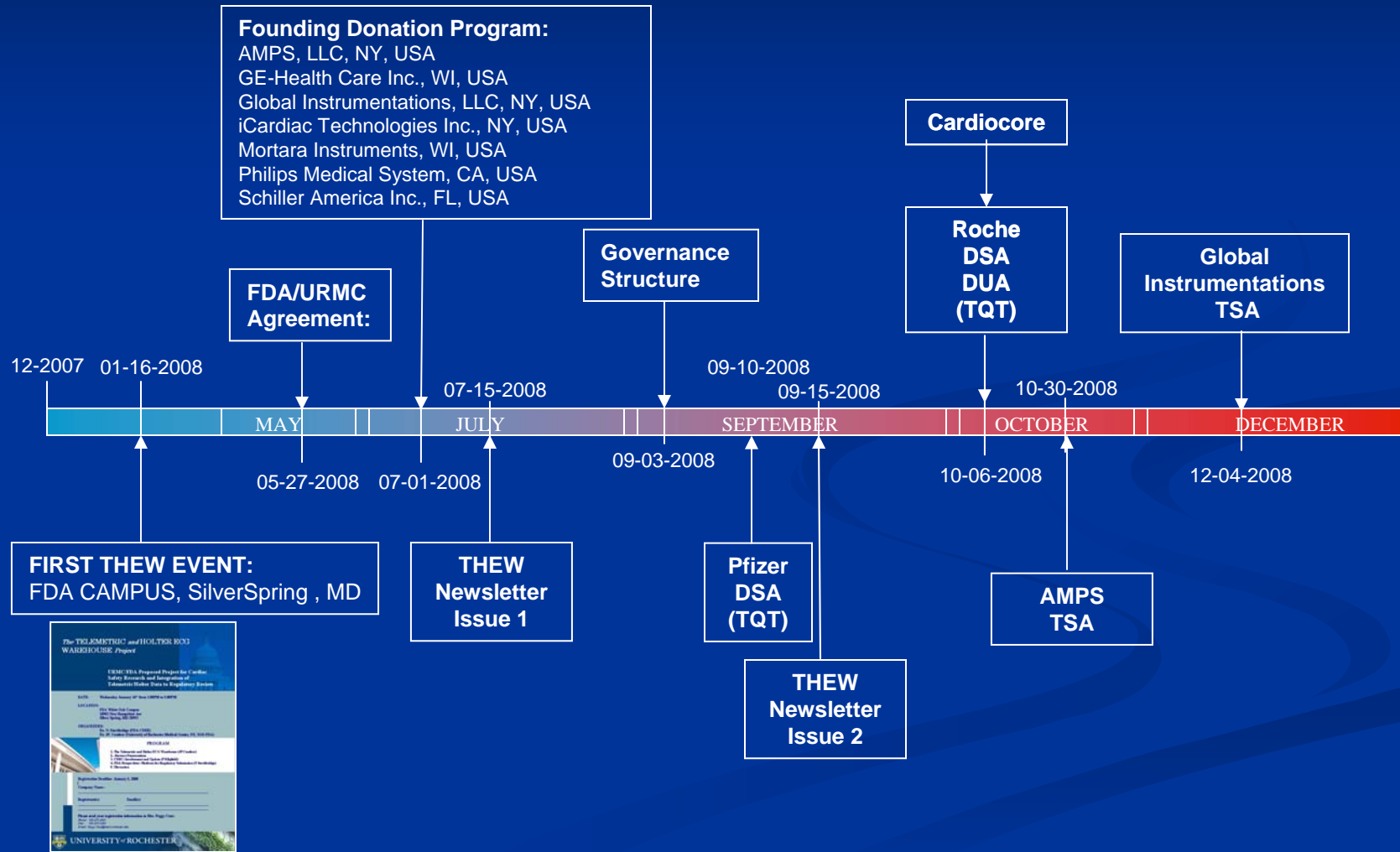
[05/27/2008] Dr. Janet Woodcock (Director, CDER-FDA) and Dr. Norman Stockbridge (Acting Director for the Division of Cardiovascular and Renal Products, CDER-FDA) signed a Letter of Agreement officially starting the partnership between the FDA and University of Rochester for the THEW initiative. [More...](#)

## FDA and University of Rochester Partnership

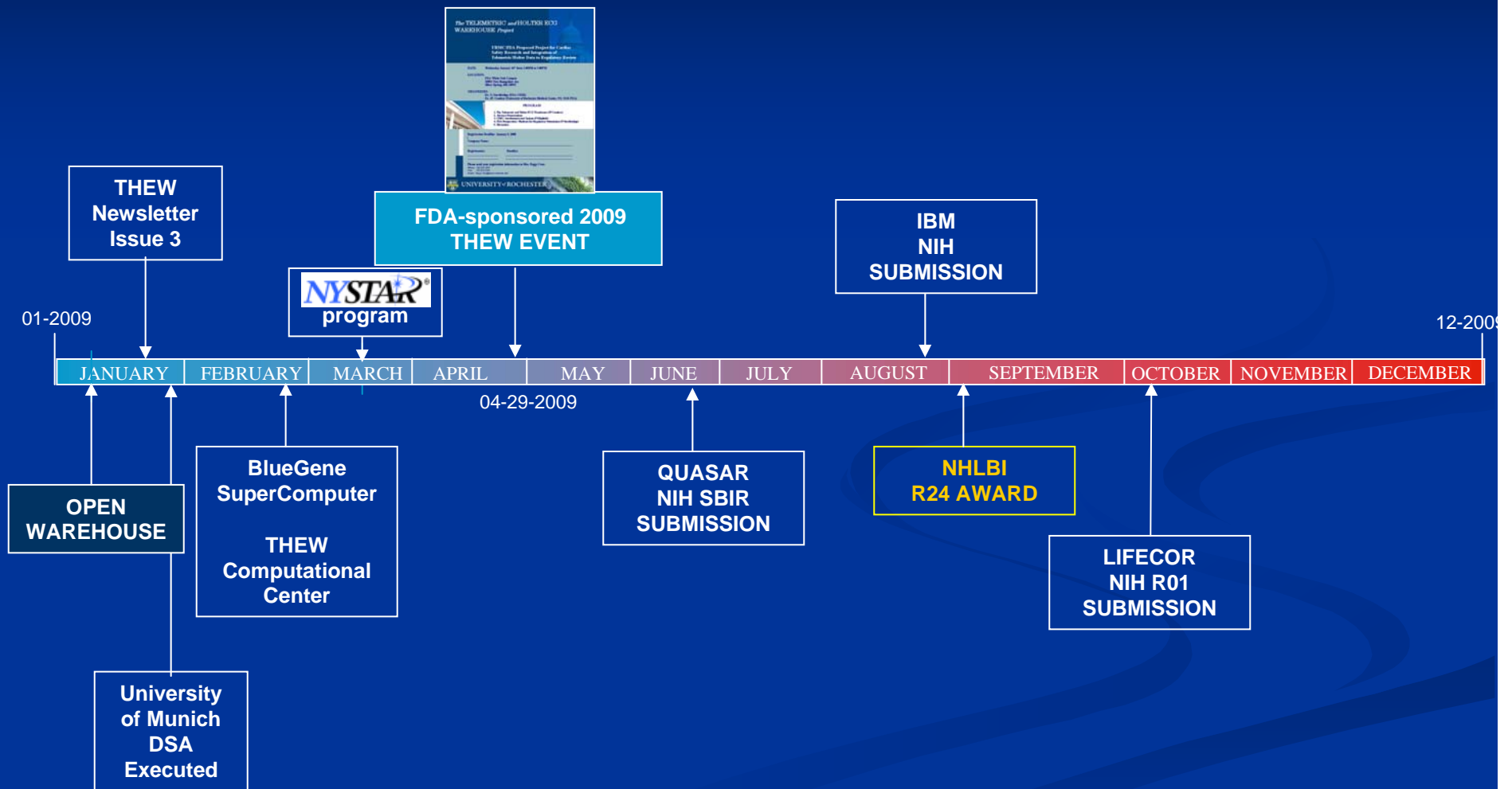
Facilitate collaborative discussions, leveraging of resources for the implementation of joint projects among FDA, UR, and other public and private stakeholders;

- Develop, identify and evaluate new electrocardiographic markers of cardiovascular risk related to management of patient care and evaluation of new molecular entities;
- As appropriate, incorporate scientific findings from the THEW into the pre-market evaluation process for ambulatory electrocardiographic devices, and into the total product life cycle.

# 2008 MILESTONES



# 2009 MILESTONES



# THEW : Data, Expertise and Tools

**Promoting cross-fertilization of scientific knowledge, resources, and ideas that will advance the field of quantitative electrocardiography**

DATA : ECGs for R&D activities

- Cardiac patients
- Healthy individuals
- Drug-induced arrhythmias
- Congenital LQTS

EXPERTISE:

- Academic Network
- Private Partners
- Others....

TOOLS:

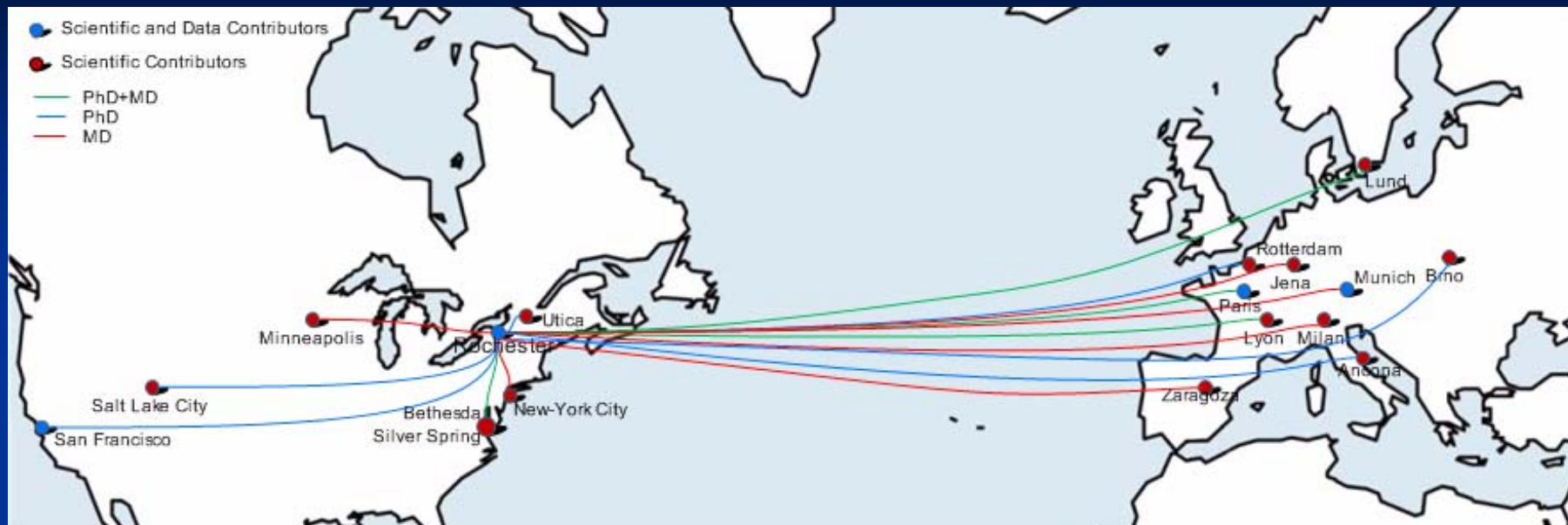
- ECG data access / visualization / APIs (Client Application)
- Computing Centers for development/validation of ECG algorithm on large database.

# THEW data: the warehouse

[1] these companies agreed on sharing the data with the THEW, legal aspect around the data sharing are being discussed.

	Study	ECG type	Contributor	# recordings	Population	
2008	IDEAL 1	24-hour Holter	HRFUP	206	Acute Myocardial Infarction	1,082
	IDEAL 2	24-hour Holter	HRFUP	265	Healthy Individuals	
	Moxifloxacin	24-hour Holter	Roche	142	Thorough QT study	
	Moxifloxacin	24-hour Holter	Pfizer	175	Thorough QT study	
	IDEAL 3	24-hour Holter	HRFUP	294	Coronary Artery Patients	
2009	Acqu. LQTS	24-hour Holter	Munich University	3	Drug-induced torsades de pointes	4,131
	Cong. LQTS	24-hour Holter	Munich University	4	Genotyped, torsades de pointes	
	Sotalol	24-hour Holter + standard ECGs	Pfizer Inc. [1]	99+1600	Baseline, single and double dose of sotalol (160/320 mg)	
	ED patients	24-hour Holter ECGs	UCSF	1308 (189 HR)	24 hour following ED admission for chest pain	
	Cardiac patients with TdPs	10-min ECGs	Munich University	34	Cardiac patients with a history of drug-induced TdPs	
2010	Healthy Volunteers	24-Holter ECGs	Abbott [1]	TBD	Pre-competitive data	9,131
	Dofetilide	24-hour Holter	Pfizer Inc. [1]	5,000	Drug-induced arrhythmias	

# THEW Expertise: Academic Network



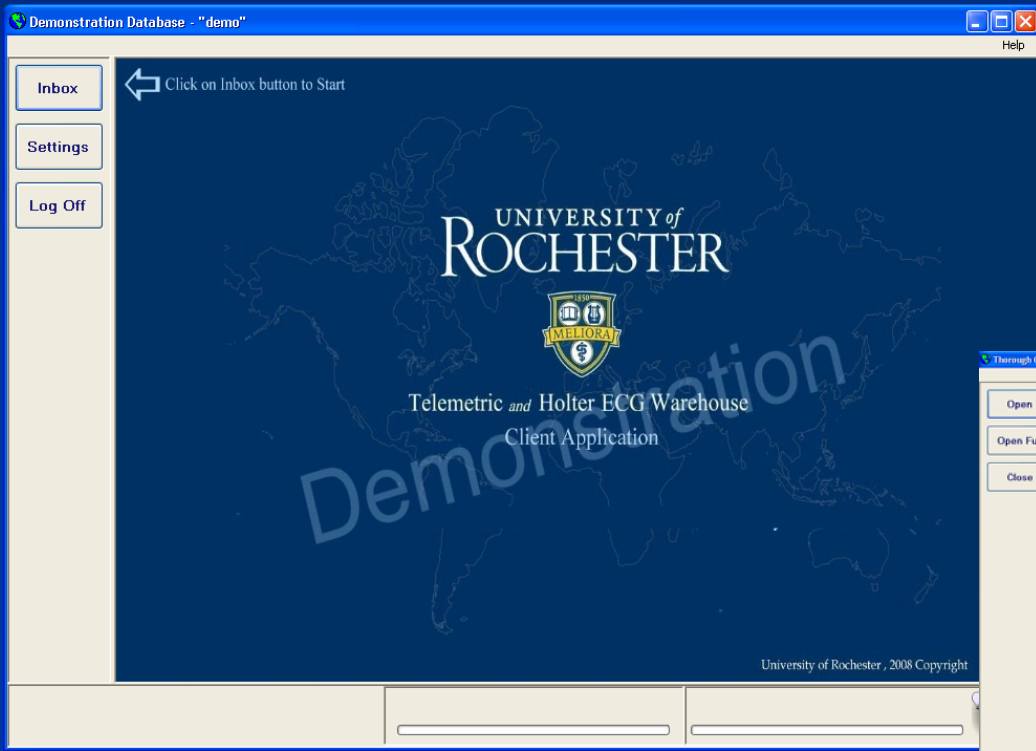
## US Committed Scientific Investigators:

(MD) Bethesda, MD - Dr. Mark Haigney, Division of Cardiology, Department of Medicine, Uniformed Services University of the Health Sciences;  
 (MD) Minneapolis, MN - Dr. Morrison Hodges, University of Minnesota;  
 (PhD) Utica, NY - Charles Antzelevitch, Masonic Medical Research Laboratory;  
 (PhD) Salt Lake City, UT - Robert Lux, CRVTI, University of Utah;  
 (PhD) Silver Spring, MD - Norman Stockbridge, CDER, FDA, US Human Health Department  
 (PhD) Rochester, NY - Mark Bocko, University of Rochester  
 (PhD) Rochester, NY - Jean-Philippe Couderc, University of Rochester Medical Center  
 (MD) New-York City - Eric Rashba, Stony Brook University Medical Center  
 (RN, PhD) San Francisco - Barbara Drew, University of California

## European Committed Scientific Investigators:

(MD) Paris, France- Pierre Maison-Blanche, Hospital Lariboisiere  
 (PhD) Milan, Italy - Alberto Porta, University of Milan  
 (PhD) Rotterdam, Netherland - Jan Kors, Erasmus MC  
 (PhD) Jena, Germany - Andreas Voss, University of Applied Sciences  
 (MD) Lyon, France - Philippe Chevalier, Hopital Louis Pradel  
 - Paul Rubel, INSA  
 (MD,PhD) Lund, Sweden - Pyotr Platonov and Dr. Fredrik Holmqvist, Lund University Hospital  
 (PhD) Ancona, Italy - Laura Burratini Polytechnic University of Marche  
 (PhD) Brno, Czech Republic, Josef Halamek , Academy of Science of Czech Republic  
 (PhD) Zaragoza, Spain, Pablo Laguna Centro Politécnico Superior. Universidad de Zaragoza

# THEW Tools: the Client Application



- Visualize ECG signals and annotations
- Download ECG signals and annotations
- Password protected access/database
- APIs empowered application
- SDK available
- Enable local machine epoch generation

Subject ID	Hook Up Date	Modified Date
6925	2/2/2008 8:03 AM	1/26/2009 12:10 PM
6905	2/2/2008 8:00 AM	2/4/2009 6:25 PM
2898	2/2/2008 7:51 AM	2/4/2009 6:28 PM
6937	2/2/2008 7:48 AM	2/4/2009 6:28 PM
7064	2/2/2008 7:42 AM	2/5/2009 5:00 PM
2887	2/2/2008 7:38 AM	1/27/2009 11:05 AM
9812	2/2/2008 7:18 AM	1/28/2009 9:41 AM
4937	2/2/2008 7:12 AM	1/27/2009 3:17 PM
3486	2/2/2008 7:03 AM	2/4/2009 8:20 PM
4548	2/2/2008 7:00 AM	2/4/2009 8:32 PM
707	2/16/2008 8:06 AM	1/13/2009 1:29 PM
4856	2/16/2008 8:03 AM	1/13/2009 12:55 PM
6905	2/16/2008 8:00 AM	1/13/2009 12:56 PM
5172	2/16/2008 7:57 AM	12/31/2008 11:24 AM
2898	2/16/2008 7:51 AM	2/4/2009 8:00 PM
5993	2/16/2008 7:45 AM	1/28/2009 9:03 AM
7064	2/16/2008 7:42 AM	2/5/2009 4:58 PM
2712	2/16/2008 7:36 AM	2/4/2009 7:52 PM
9812	2/16/2008 7:18 AM	1/28/2009 2:33 PM
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5035	2/16/2008 6:54 AM	2/4/2009 8:50 PM
1317	2/16/2008 6:46 AM	1/27/2009 9:41 AM
5588	2/16/2008 6:42 AM	1/28/2009 8:39 AM
470	2/16/2008 6:33 AM	1/27/2009 3:44 PM
4641	2/16/2008 6:30 AM	1/27/2009 2:21 PM
707	2/9/2008 8:06 AM	1/12/2009 2:38 PM
2272	2/9/2008 7:54 AM	2/4/2009 8:11 PM
6937	2/9/2008 7:48 AM	1/28/2009 10:06 AM
2887	2/9/2008 7:39 AM	2/4/2009 7:57 PM
3365	2/9/2008 7:33 AM	2/4/2009 8:14 PM
8473	2/9/2008 7:15 AM	1/28/2009 12:10 PM
4937	2/9/2008 7:12 AM	1/27/2009 3:03 PM
4548	2/9/2008 7:00 AM	1/27/2009 1:40 PM
4818	2/9/2008 6:57 AM	1/27/2009 2:48 PM
5035	2/9/2008 6:54 AM	1/28/2009 7:55 AM
5588	2/9/2008 6:42 AM	1/28/2009 8:25 AM

The version of the THEW Client Application (V1.4) is tested on site at the FDA and in 20 sites in the U.S. and in Europe.

Free demo version available at [www.thew-project.org](http://www.thew-project.org)

# THEW Tools: the Client Application

## Thorough QT study: E-HOL-12-140-008

File format for ECG signal and annotation:

- 1/ ASCII format
- 2/ ISHNE format
- 3/ FDA-XML (coming up)

Selection of extracted period, no limitation in duration.

The screenshot displays the THEW Tools Client Application interface for a Thorough QT study. The main window is titled "Thorough QT study #2 - 'tqt2'" and features a sidebar with navigation buttons: "R-R Tachogram", "Full Disclosure", "Close", "Download ECG", and "Study Info".

The "R-R Tachogram" section shows two plots of R-R intervals over time. The top plot covers a 24-hour period from 8:00 to 8:00 on Sunday, with a vertical green bar highlighting a specific period around 16:00. The bottom plot is a zoomed-in view of this period, showing R-R intervals from 16:00 to 16:50. Below the plots are navigation buttons: "<< Previous", "Next >>", and "Delete Epoch".

The "Download ECG" section provides options for exporting data. It includes a "Time Period" section with "Start Time" and "End Time" fields (format: hh:mm:ss am/pm) and a "Whole Recording" checkbox. Below this is an "Epoch List" section with a "Get Epoch" button and a list of epochs. The list shows epochs 4056 through 4060, each with a relative time and a "RelativeTime-False" status. Below the list are "Download As Text" and "Download As Ishne" buttons.

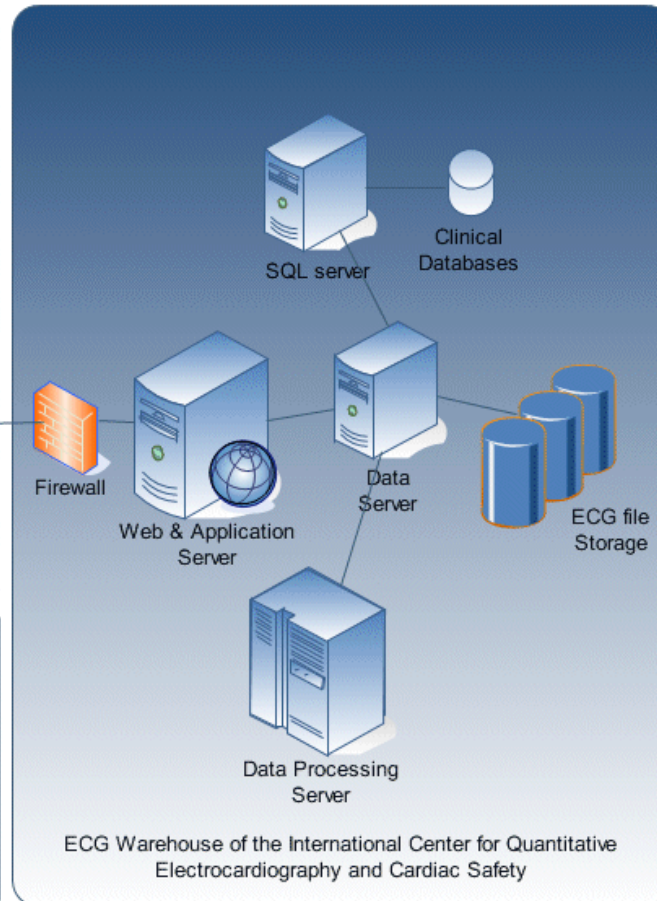
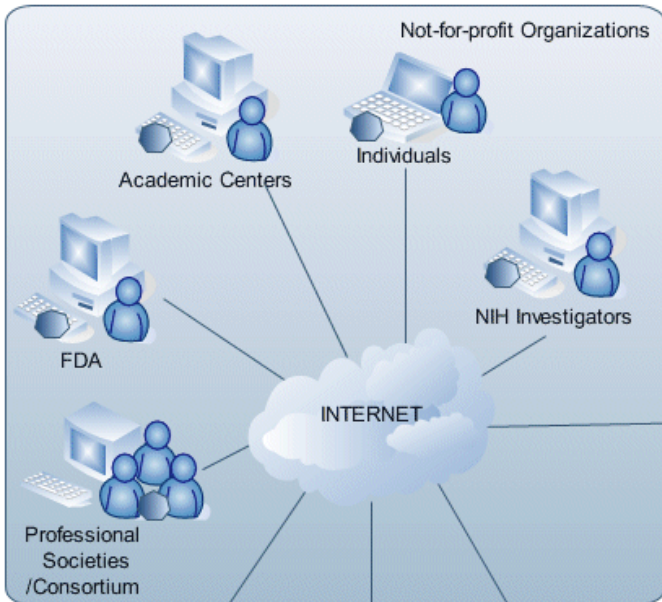
The bottom right of the interface shows a 12-lead ECG plot for "4:59:24 PM Saturday" with lead labels (N, 1105, 1067, 1039, 1122, 1090, 1133, N) and "X Caliper" and "Y Caliper" buttons.

# Conclusions

- **Our heritage** is the Heart Research Follow Up Program that has extensive experience in the design, conduct, and analysis of world-wide, multicenter, clinical research studies ranging from 100-3,500 subjects (MADIT I, MADIT II, MADIT CRT, LQTS and ARVD registries).
- **Our alignment** with the Critical Path Initiative has been officially expressed by a partnership agreement between the University of Rochester and the FDA - a 3-year partnership for the development of ECG technologies within the drug safety arena.
- **Our objective** is to promote cross-fertilization of scientific knowledge, resources, and ideas that will advance the field of quantitative electrocardiography.
- The THEW will play an important role in the development of novel ECG technologies by helping the access to scientifically relevant ECG recordings and their clinical information.

# THEW

## THEW Users



THEW Client Application

# Disclaimer

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