Using 2007 Informatics for Post-marketing Surveillance

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Children's Hospital Informatics Program
Harvard-MIT Health Sciences and Technology
Harvard Medical School Center for Biomedical Informatics

The Impossible Task

The FDA needs to get innovative drugs and devices to market quickly . . .

. . . while protecting the public from any adverse effects of those drugs and devices

But, the perfect is the enemy of the good, so let's try anyway

Lessons learned from biosurveillance

	Outbreak Detection	Drug Safety Surveillance
Crisis precipitant	Anthrax	Vioxx
Approach	Manual reporting	Manual reporting
Limitations	**Possible bias in reporting** **Delays in reporting** **Incomplete reporting** **Limited automation** **Limited communication systems**	**Possible bias in reporting** **Delays in reporting** **Incomplete reporting** **Limited automation** **Limited communication systems**
Action Arm	Shoe leather epidemiology	Dear Dr. Letters, Label change
Evolution	Biosurveillance	Sentinel Network

http://aegis.chip.org

https://server.aegis.chip.org - Home View - Mozilla Firefox

AEGIS HARVARD MEDICAL SCHOOL Children's Hospital Boston

Help Logout

SELECT DATE

SELECT HOSPITAL/SYNDROME

	MGH	AGH	ALL	MA	BEV	BIDMC	CHB
RESP							
GI							
RASH							
NEURO							
HEMOR							
ALL							
INJ							

SELECT ABBERRATION

Aberrations For Current Selection

MGH	RESP	S 9/7	details	export

Other Aberrations

MGH	RESP	S 9/7	details	export
MGH	RESP	S 9/6	details	export
CHB	RESP	S 8/26	details	export
SSHORE	GI	T 9/1	details	export

LEGEND

Active Inactive
- Normal
- Aberration (99% Certainty)
- Aberration (99.9% Certainty)
- Result not yet available

S/T - Spatial/Temporal Aberration

Map Satellite Hybrid

Malden Revere Everett Chelsea Waltham Somerville Cambridge Watertown Boston Newton

Map data ©2006 Tele Atlas - Imagery ©2006 MassGIS, Commonwealth of Massachusetts EOEA, DigitalGlobe - Terms of Use

TEMPORAL HISTORICAL

Aberration (99.9% Certainty) Aberration (99% Certainty) Normal - - Predicted Visits
Observed Visits

Done

Sentinel Network Building Blocks

Sentinel Network Building Blocks

Data acquisition

- Challenges:
  - ✓ Much electronic information is in free text
  - ✓ PBM data are not necessarily complete

PBM Data Errors

CLOBETASOL 0.05% SOLUTION	08/03/2006 08/03/2006
HUMALOG 100 UNITS/ML VIAL	03/11/2006 07/28/2006
ONE TOUCH ULTRA TEST STRIPS	03/11/2006 07/28/2006
METHIMAZOLE 10 MG TABLET	05/16/2006 05/16/2006
HUMULIN N 100 UNITS/ML VIAL	04/21/2006 04/21/2006
BD INS SYR UFII 0.5 ML 31X5/16	01/02/2006 03/29/2006

PBM Data Errors

CLOBETASOL 0.05% SOLUTION	08/03/2006 08/03/2006
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HUMULIN N 100 UNITS/ML VIAL	04/21/2006 04/21/2006
BD INS SYR UFII 0.5 ML 31X5/16	01/02/2006 03/29/2006

4 months ago, patient switched to a pump which is not dispensed through usual mechanism.

PBM Data Errors

CLOBETASOL 0.05% SO	8/03/2006
HUMALOG 100 UNITS/M	7/28/2006
ONE TOUCH ULTRA T STRIPS	7/28/2006
METHIMAZOLE 10 MG TABLET	05/16/2006 05/16/2006
HUMULIN N 100 UNITS/ML VIAL	04/21/2006 04/21/2006
BD INS SYR UFII 0.5 ML 31X5/16	01/02/2006 03/29/2006

Actually, patient was lowered to 5mg/day, but did not get the script changed.

Data acquisition

- Challenges:
  - ✓ Much electronic information is in free text
  - ✓ PBM data are not necessarily complete
  - ✓ Privacy

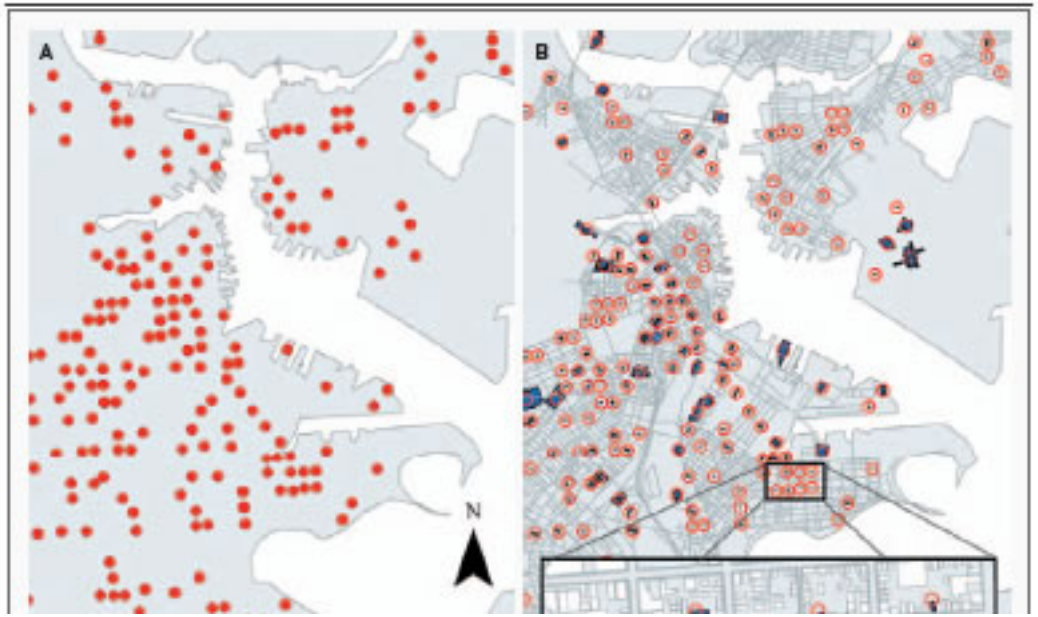
NEJM 2006

CORRESPONDENCE

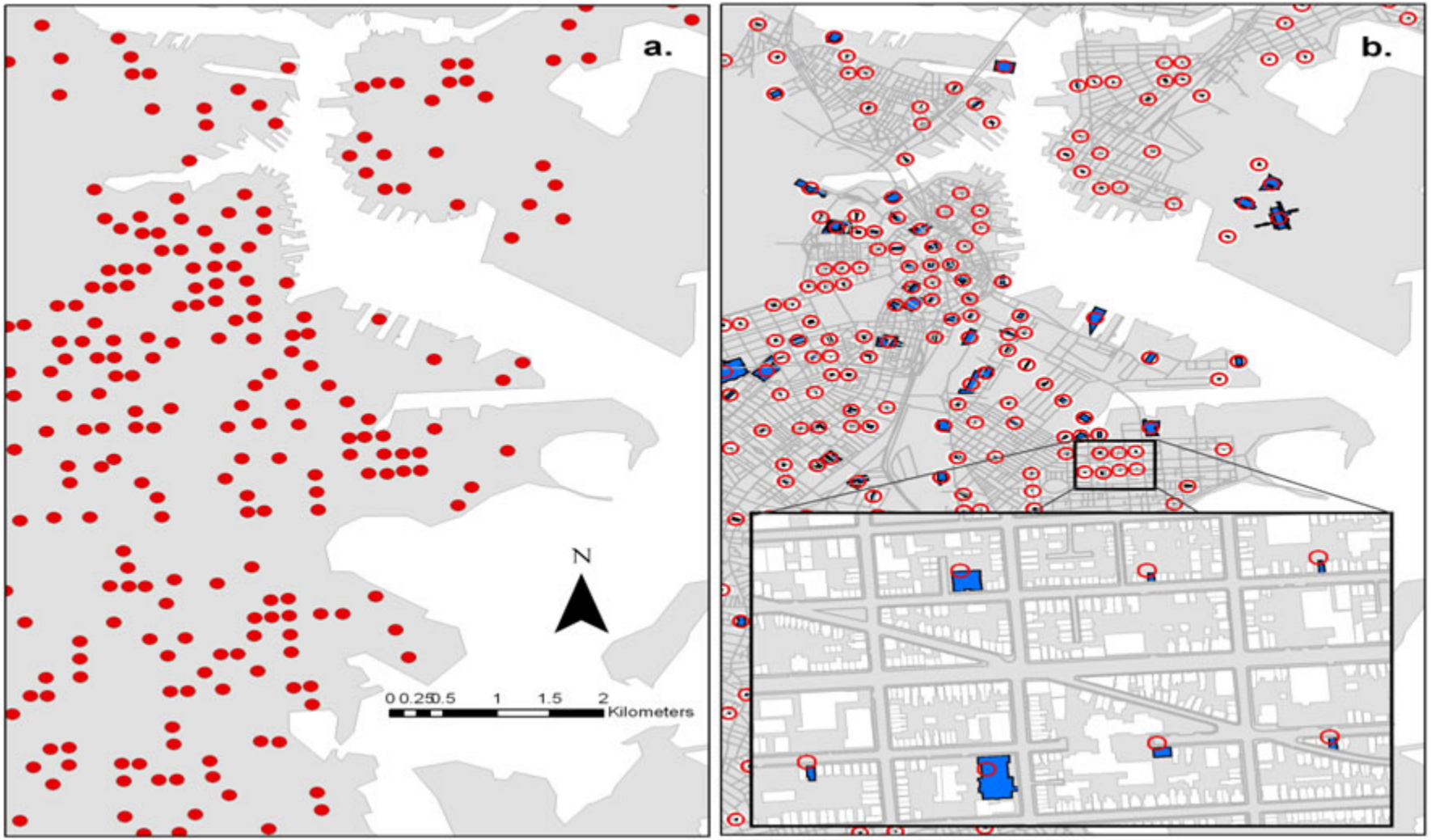
No Place to Hide — Reverse Identification of Patients from Published Maps

TO THE EDITOR: The mapping of health data is now widespread in both academic research and public health practice.[1] Although the notion that location influences the risk of disease dates back to the mapping of yellow fever and cholera in the 1800s, research that integrates maps with human health is an emerging field based on the widespread availability of geographic information system (GIS) software.[2] Such systems have broad applicability, and their use has been fueled by the availability of increased computing power, user-friendly software, and large geographic databases. The number of publications that use GIS data for health research has grown by about 26% per year, four times the rate of increase in the number of articles on human health in general.[2] Patients' addresses are mapped to identify patterns, correlates, and predictors of disease. These maps are then published electronically and in print.[1]

Using keyword searches for the terms "geographic" and "map" in the figure legends of articles in five major medical journals published



Re-identified



Data acquisition

- Challenges:
  - ✓ Much electronic information is in free text
  - ✓ EMR and PBM data are not necessarily complete
- Opportunities:
  - ✓ Process the free text--NLP Tools
  - ✓ PCHRs
  - ✓ Models for regional and national data sharing are evolving - National Health Information Infrastructure

I2B2 National Center for Biomedical Computing

www.i2b2.org

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Informatics for Integrating Biology & the Bedside

A National Center for Biomedical Computing

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Resources

- Overview
- The Hive
- Genomic Minicourses
- Computational Tools
- Data Sets
- Methodologies Compendium
- How to list
- De-Identification Demo

The Hive

The most important challenge of i2b2 is to disseminate the computational tools, methodologies, biomedical data sets and educational materials widely within the biomedical and computational research communities. To do so we have committed to make all the resources freely available to all interested parties. In this section you will find access to all of these. We would appreciate referencing i2b2 if you do choose to use these resources. The preferred method of citation or reference is provided in each subsection. Please note that for some resources (e.g. software) the use of the resource requires accepting a specific (e.g. OpenSource) license. Please read the particulars of each license to see how it might impact your current and future use.

i2b2 Hive

Hover over cells below to view resources

Project Management

File Repository

Ontology Management

Data Repository (CRC)

Annotating Genomic Data #1

Natural Language Processing

De -

Annotating Genomic Data #2

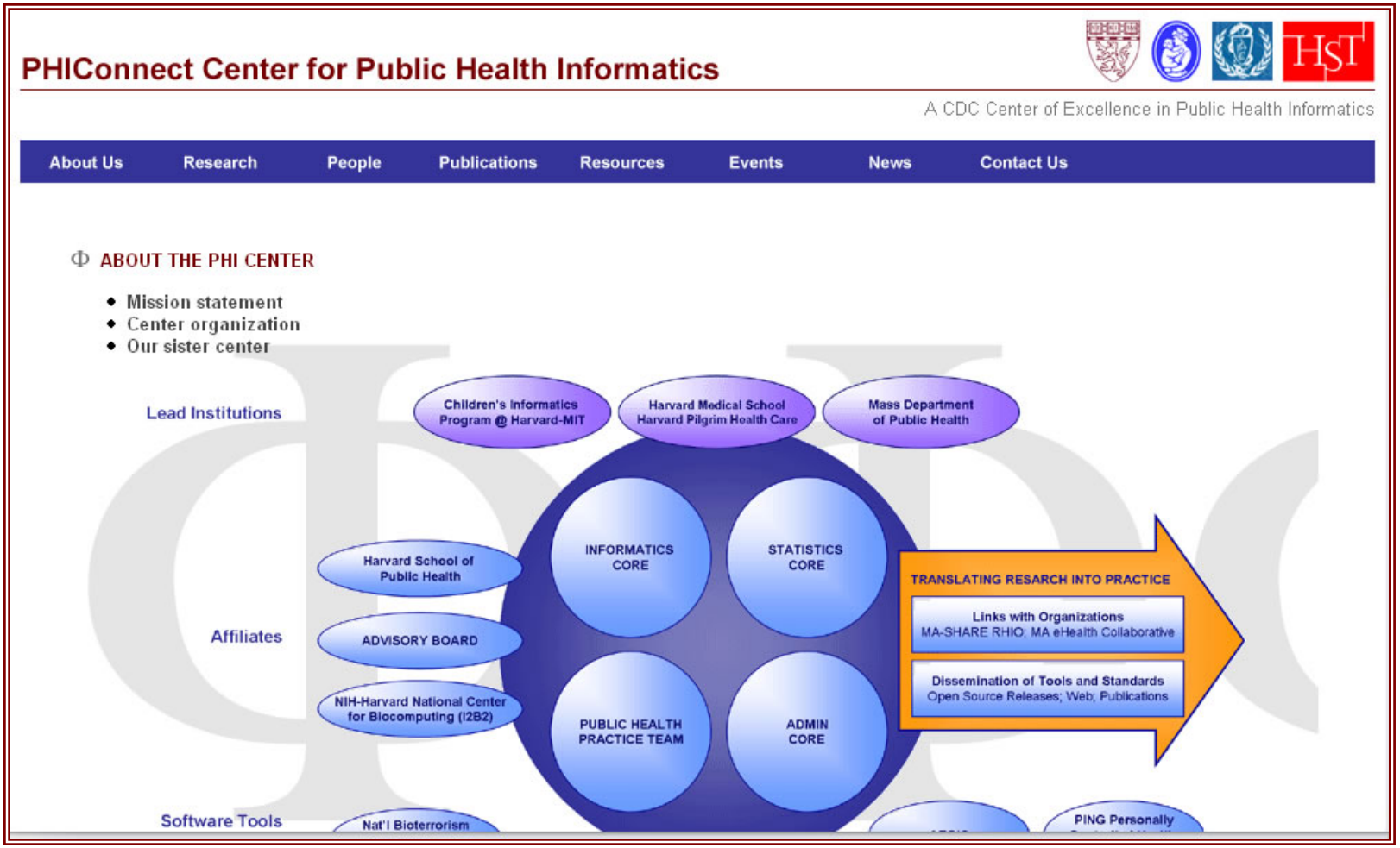
Natural Language Processing Cell

This cell manipulates text reports to extract specific terms and knowledge from them. These concepts are then used to achieve various representations of the data.

Click to view the following:

PDF XSD Code Demo

PHIConnect
CDC Center of Excellence in Public Health Informatics



www.phiconnect.org

Indivo PCHR www.indivohealth.org

http://demo.indivohealth.org – Indivo – Personally-Controlled Health Record

JOHN CHILD

INDIVOHEALTH PERSONALLY CONTROLLED HEALTH RECORD

MESSAGES | SUBSCRIPTIONS | EXPORT RECORD | SHARING | LOG OUT

My Indivo Record childl@indivohealth.org

HOME

PERSONAL
- CONTACT INFO
- OTHER CONTACTS
- INSURANCE

SUMMARY
APPOINTMENTS
CLINICAL NOTES
LAB TESTS
IMMUNIZATIONS
MEDICATIONS
PROBLEM LIST
VITAL SIGNS
SURVEYS

Patient Summary DOB: 12-Jan-04

PROBLEM LIST
- Sore throat

LAB TESTS
- 18-Jul-05 – Complete Blood Count with Differential
- 18-Jul-05 – Lead (Pb)
- 18-Jul-05 – Reticulocyte, Cell Hemoglobin
- 18-Jul-05 – Differential, manual

VITALS
- No Vitals

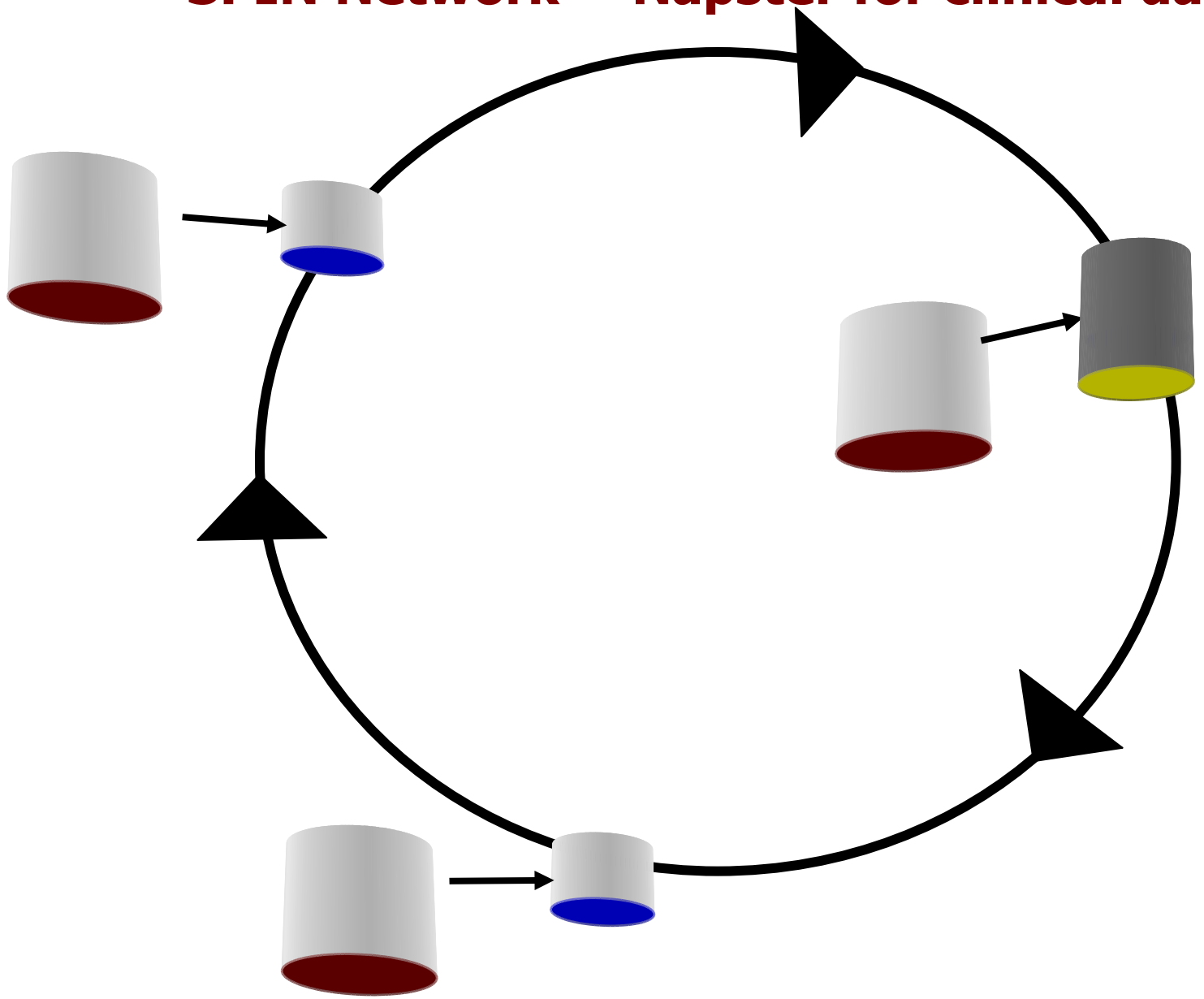
MEDICATIONS
- Loratadine

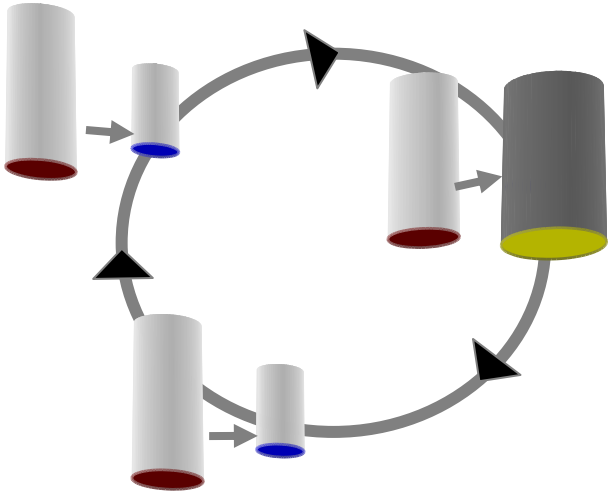
EQUIPMENT
- No Equipment

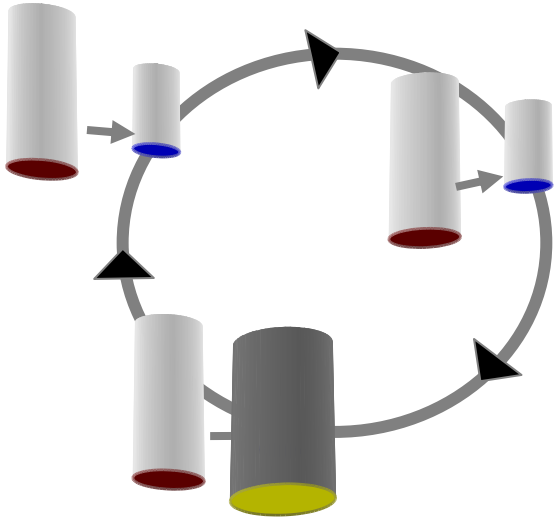
IMMUNIZATIONS
- poliovirus, live, oral – Seq. 1
- poliovirus vaccine, inactivated – Seq. 1
- Haemophilus influenzae type b vaccine, conjugate NOS – Seq. 3
- Haemophilus influenzae type b vaccine, conjugate NOS – Seq. 2
- Haemophilus influenzae type b vaccine, conjugate NOS – Seq. 1
- Bacillus Calmette-Guerin vaccine – Seq. 1
- diphtheria, tetanus toxoids and acellular pertussis vaccine – Seq. 3
- diphtheria, tetanus toxoids and acellular pertussis vaccine – Seq. 2
- diphtheria, tetanus toxoids and acellular pertussis vaccine – Seq. 1
- hepatitis B vaccine, NOS – Seq. 4
- hepatitis B vaccine, NOS – Seq. 3
- hepatitis B vaccine, NOS – Seq. 2
- hepatitis B vaccine, NOS – Seq. 1
- pneumococcal conjugate vaccine, polyvalent – Seq. 3

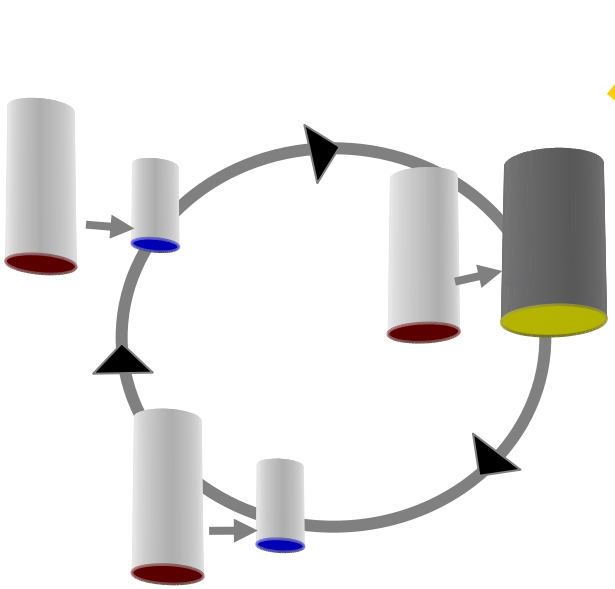
Done Adblock

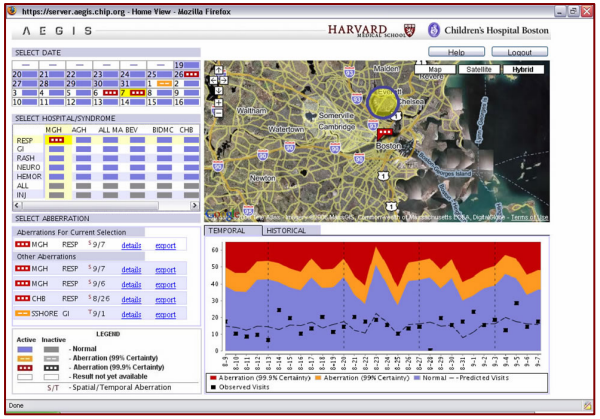
SPIN Network—"Napster for clinical data"







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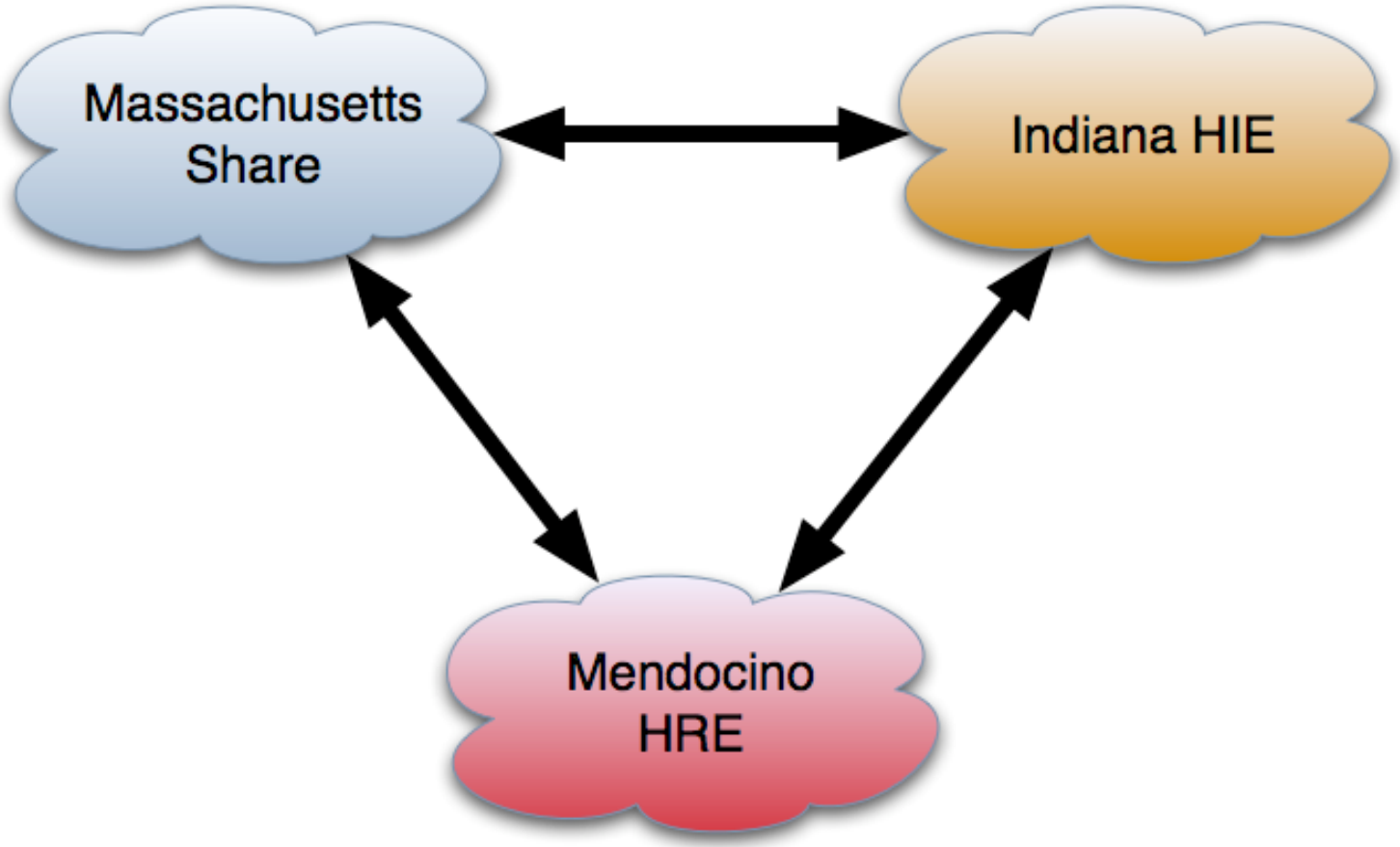
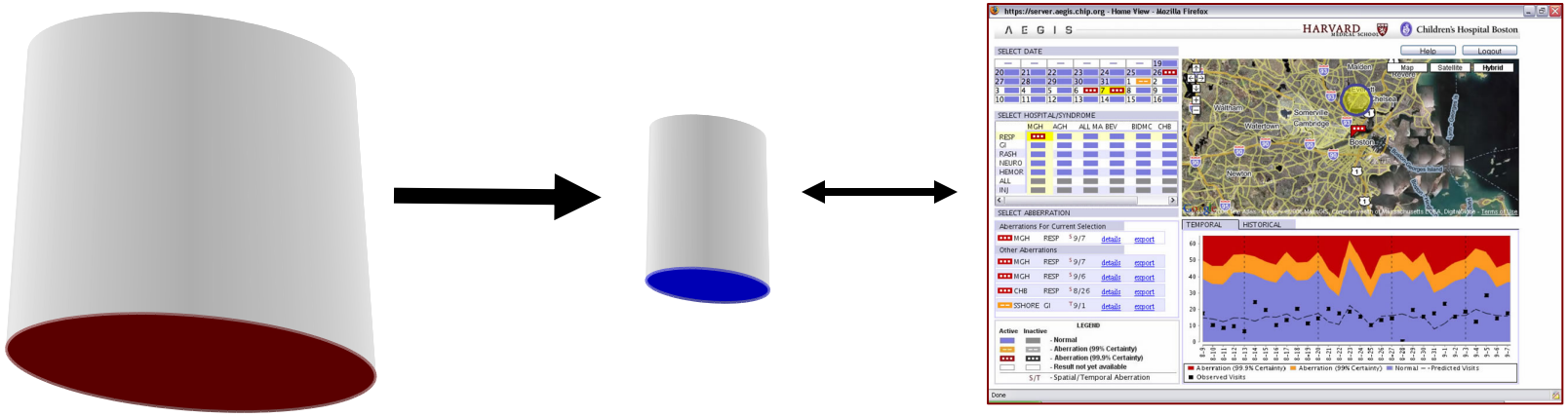
Logout
SELECT DATE
SELECT HOSPITAL/SYNDROME
SELECT ABBERRATION
Aberrations For Current Selection
Other Aberrations
LEGEND
TEMPORAL
HISTORICAL
Map
Satellite
Hybrid
Done

2007 AHIC/ONC/NHIN Demonstration

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MGH AGH ALL MA BEV BIDMC CHB
RESP
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CHB RESP 8/26 details export
SSHORE GI 9/1 details export
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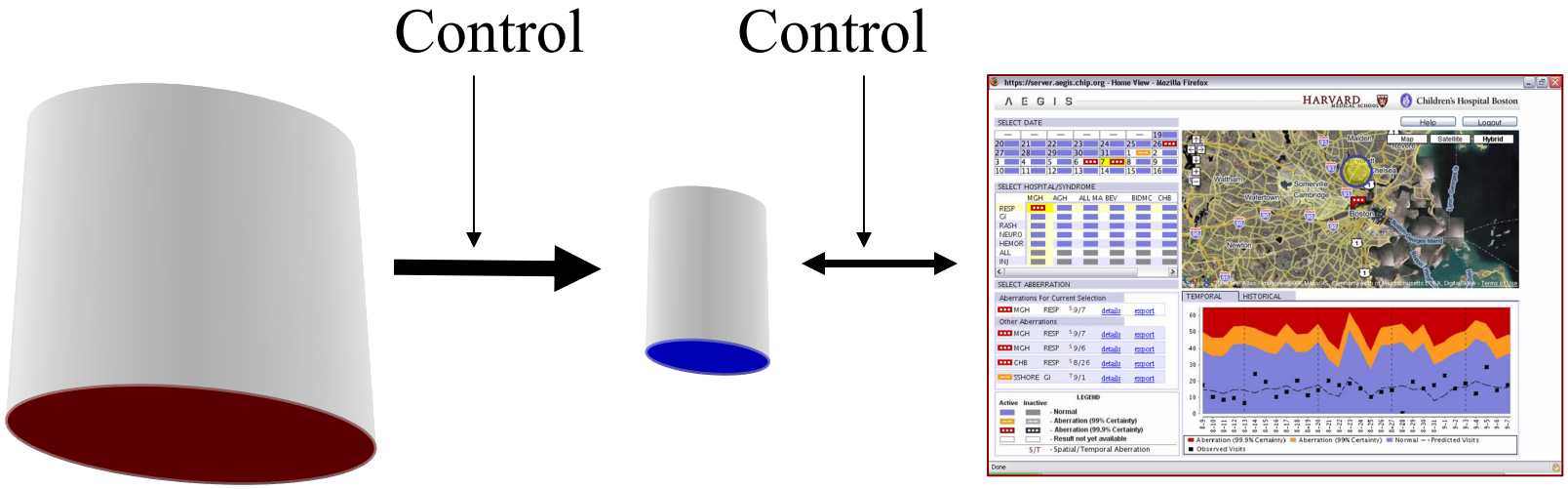
S/T - Spatial/Temporal Aberration
TEMPORAL
HISTORICAL
Aberration (99.9% Certainty)
Aberration (99% Certainty)
Normal
Predicted Visits
Observed Visits
Done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Control
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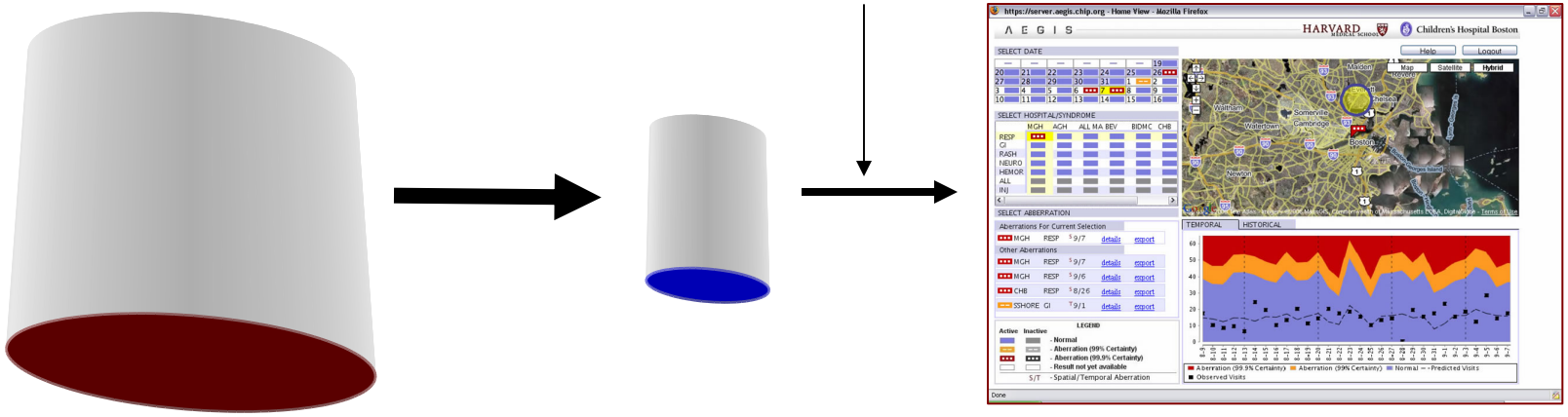
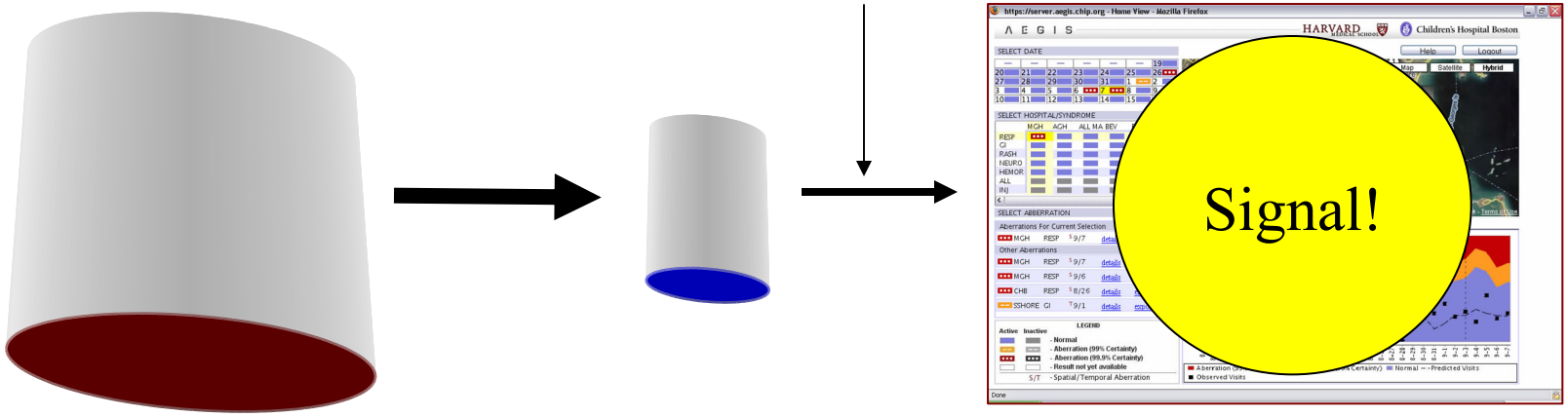
Children's Hospital Boston
SELECT DATE
SELECT HOSPITAL/SYNDROME
SELECT ABBERRATION
TEMPORAL
HISTORICAL

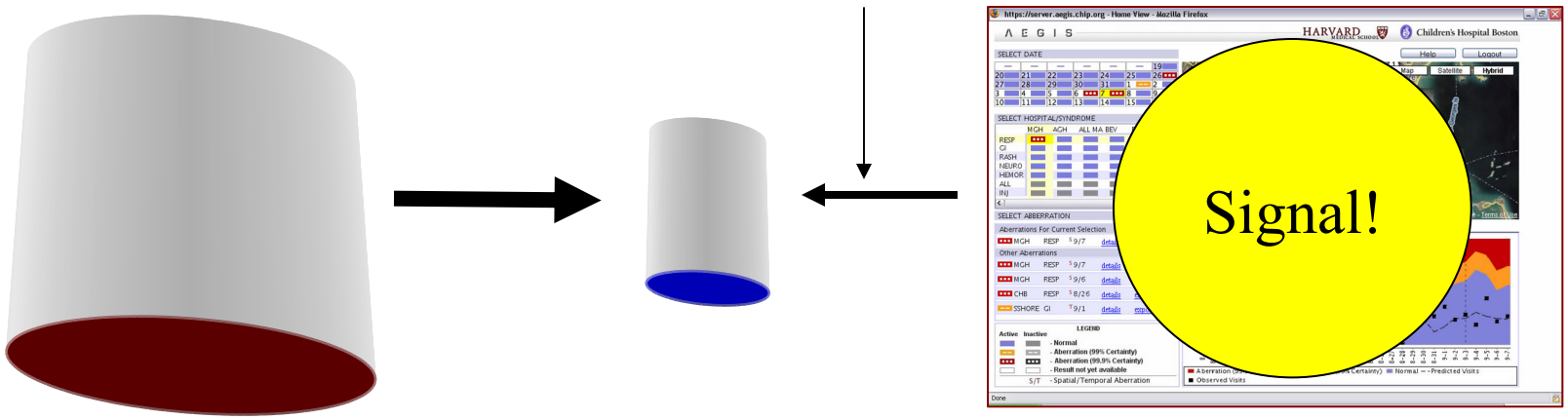
Anonymized data



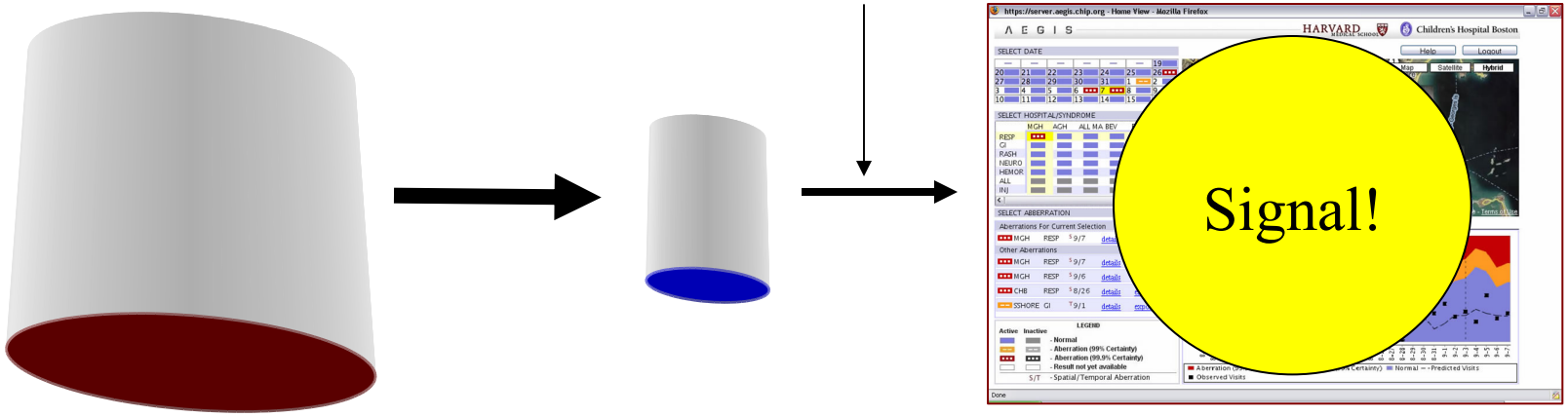
Anonymized data

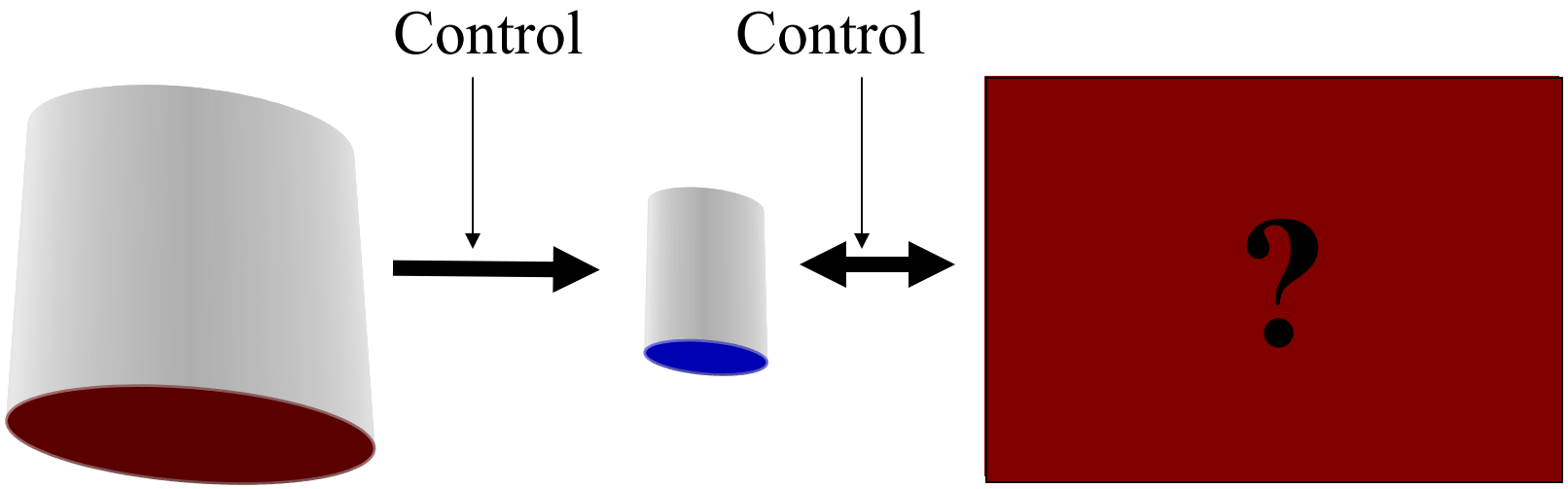


Query under public health authority



Return appropriate data (based on prior agreement)




Control
Control
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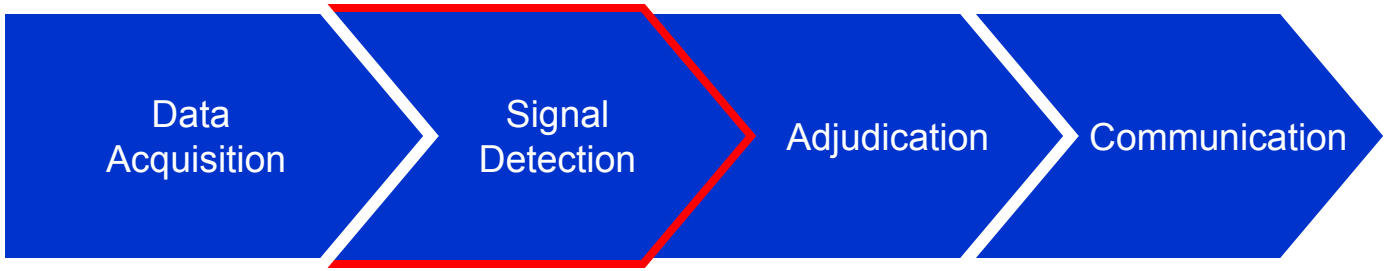
Signal detection



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Children's Hospital Informatics Program at the Harvard-MIT Division of Health Sciences & Technology

Clinical and Public Health Informatics Group

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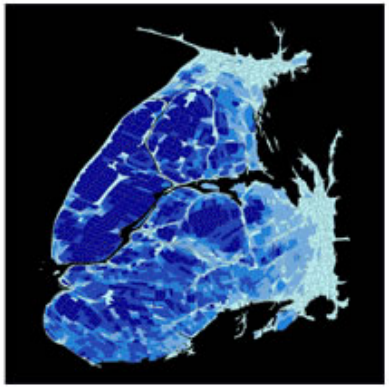


Welcome

Our group studies the application of medical informatics, computer science, epidemiology, and biostatistics to improve public health and clinical practice. Please see a detailed listing of our **Research Projects** and **Publications**.

Our public health informatics research focuses on biosurveillance and population health monitoring, influenza and infectious disease epidemiology, pharmacosurveillance, and geographical information systems (GIS). Our clinical informatics research focuses on personally controlled health records, clinical prediction and decision making, and advanced health communication infrastructures.

We also develop practical technologies deployed in real-world settings, including the AEGIS real-time surveillance system and the IndivoHealth personally controlled electronic medical record.

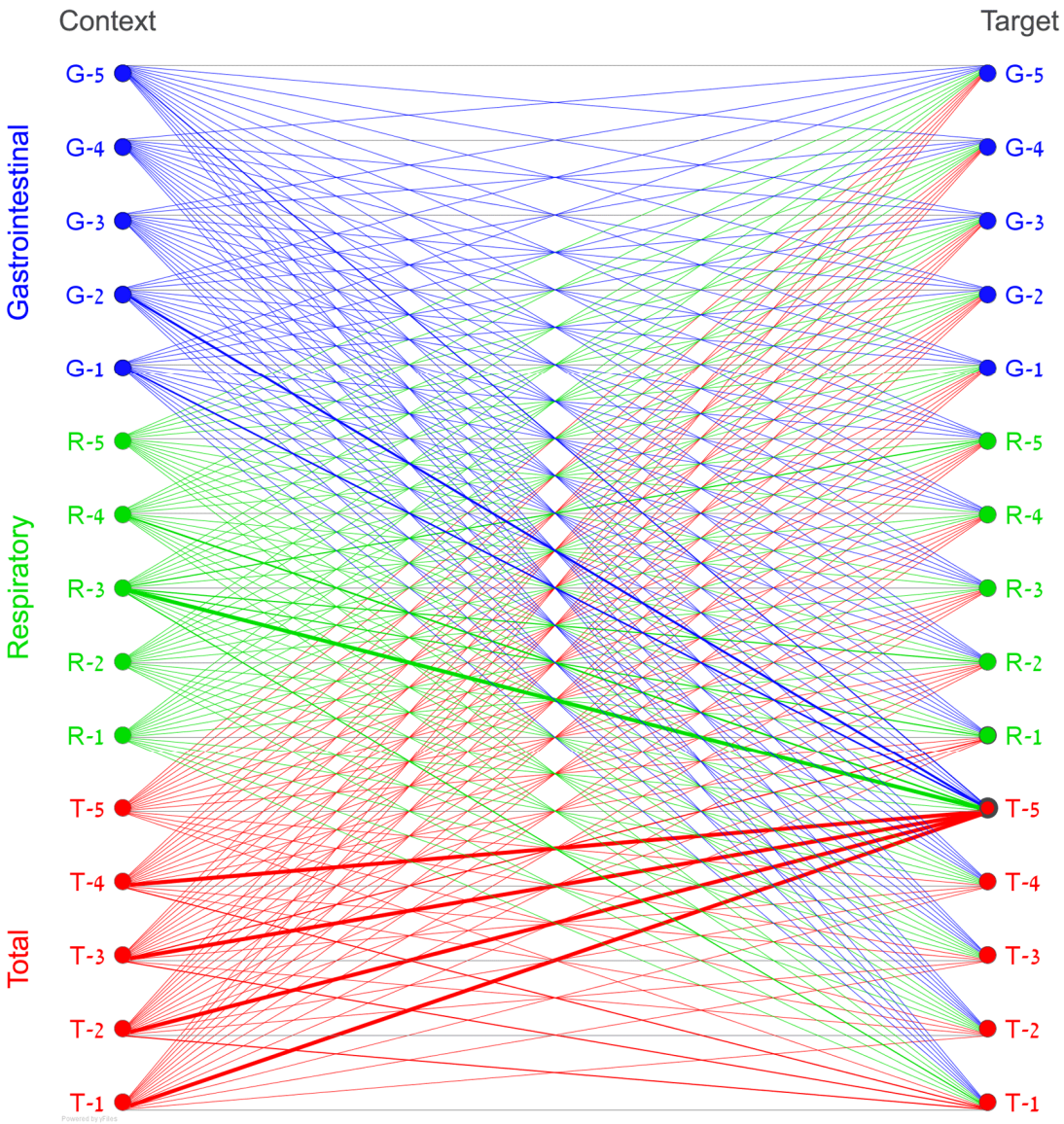
News

01/19/2007. Dr. Mandl discusses personal health records on NPR's Marketplace.

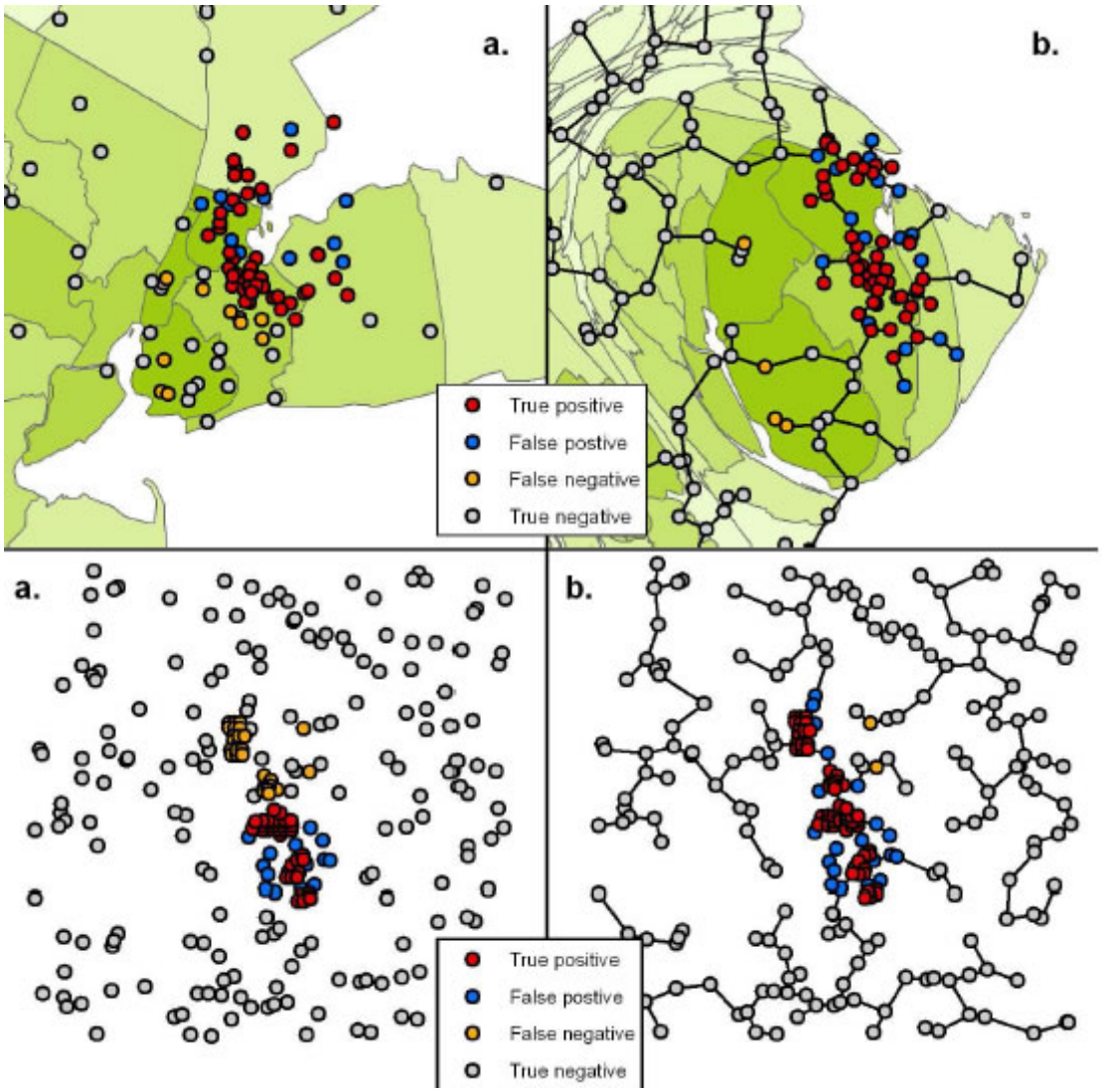
12/01/2006. HEALTHmap featured in Science News.

10/27/2006. Personnally Controlled Health Records: Are They the Next Big

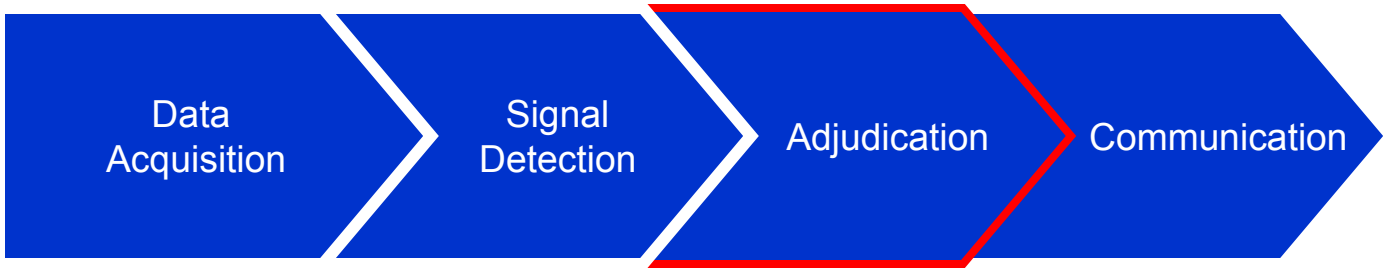
Multivariate surveillance-network models



Spatial signal detection



Adjudication



Adjudication

- Challenges
  - ✓ There is *always* a tradeoff between early detection and false alarms
  - ✓ Real economic and public health dangers of impugning a medication
  - ✓ Engaging pharma, healthcare, academia and government *together* on this process
- Opportunities
  - ✓ Provide maximum information for making decisions
  - ✓ ***Open methods***
  - ✓ Provide open and safe environment, ideal for making decisions

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Frank L. Douglas, PhD, MD, Executive Director, MIT-CBI

Collaborative Innovation > Transformational Impact

- CBI's **collaborative** model invites experts from industry, government and academia together to create and sustain a unique **Safe Haven** environment, where they can share ideas, conduct research and educate for action.
- We challenge existing assumptions about the **pre-competitive space**, working to understand where the benefits of information sharing in the evolving industry outweigh the competitive risks.
- Our research success metrics focus on real world **implementation** across the entire innovation chain, resulting in **transformation of the system**.

Welcome

Led by Frank L. Douglas, Ph.D., M.D., the **CBI mission is to transform** the discovery, development, manufacture and distribution of cost-effective therapeutics and devices. To achieve this, we have created a 'safe haven' in which academic, government and industry experts communicate and collaborate to generate and disseminate high-impact systemic solutions that enhance efficacy, safety, and quality of patient care, worldwide.

News and Events

Events

April 11, 2007: Dr. Frank L. Douglas to receive the 2007 Black History Makers Award from Associated Black Charities

March 1, 2007: Dr. Frank L. Douglas to speak on "The Innovation Challenge

Highlights

CBI announces collaboration with FDA on drug safety monitoring: "Under this collaboration, CBI will work to identify alternative methods for monitoring the safety

Communication

Communication

- The challenges:
  - ✓ It is difficult to get the most complete information out to the people who need it in a timely fashion
- The solutions:
  - ✓ Tailored and targeted communication
  - ✓ Leverage experience from PCHRs, etc

Summary: Areas for Focus

- **Computational Informatics**
  - ✓ Clinical Intelligence
- **Industrial-Societal Interface**
  - ✓ Engagement of Pharms
- **Medical Informatics**
  - ✓ Data exchange