



Building a Scientific Community for the Learning Health System

Learning Health Systems: Lessons from Distributed Health Data Networks

48th Hawaii International Conference on System Sciences
Learning Health System Symposium

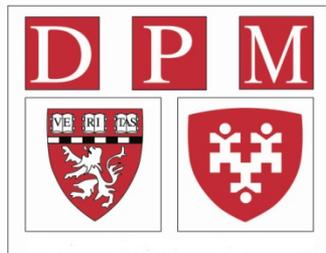
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January 2015

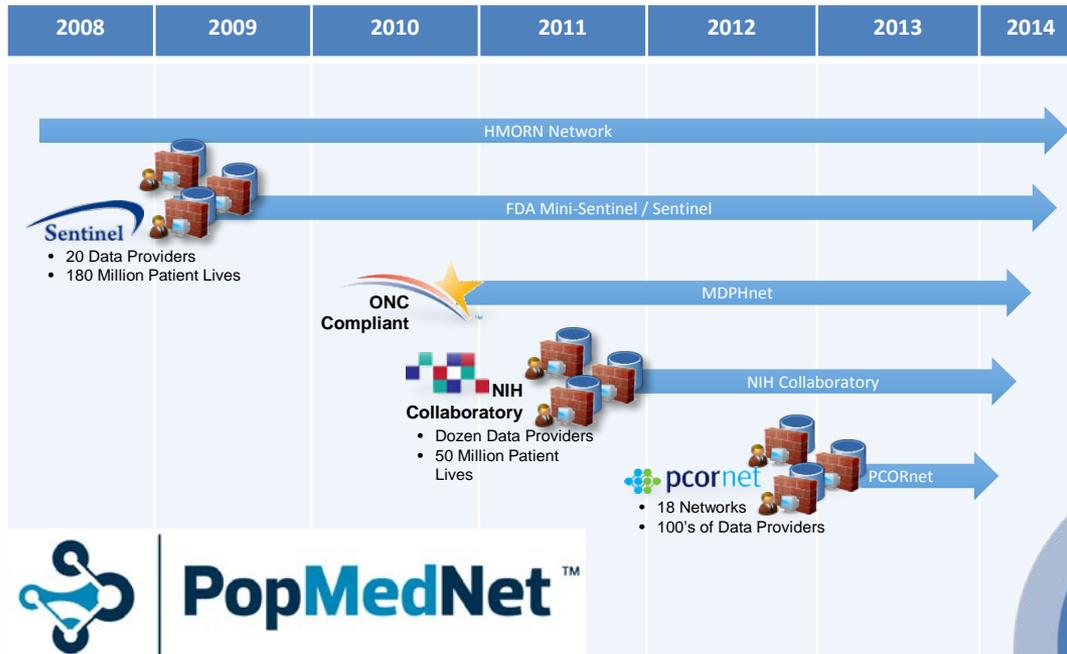


Outline

- View of a Learning Health System
- Distributed Health Data Networks
- Lessons from the Field
 - Mini-Sentinel
- Core Opportunities

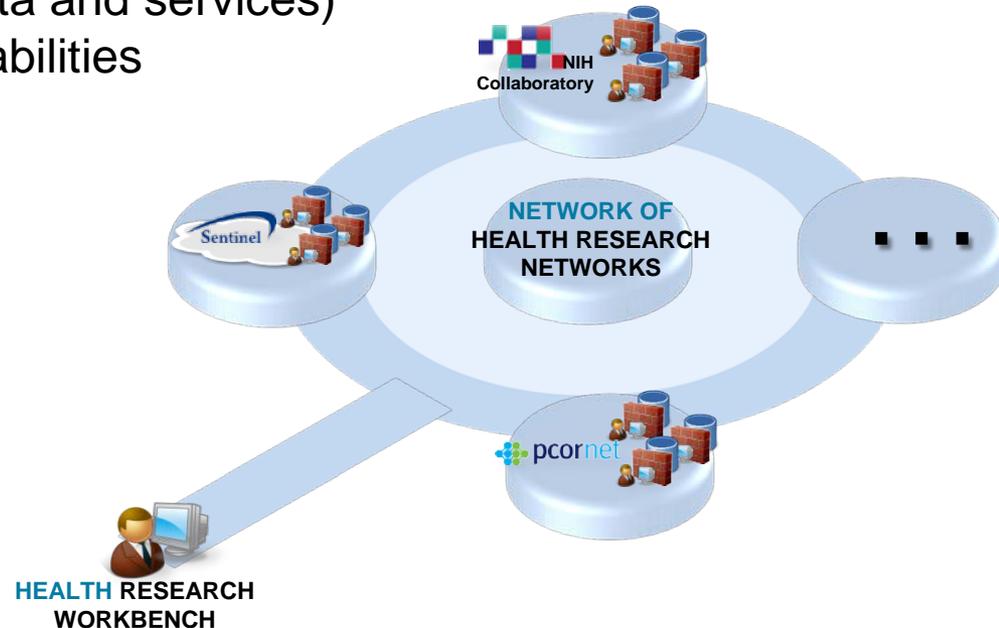
Vision of a Learning Health System

Spent last several years designing and building health data research networks for multiple purposes



Vision of a Learning Health System

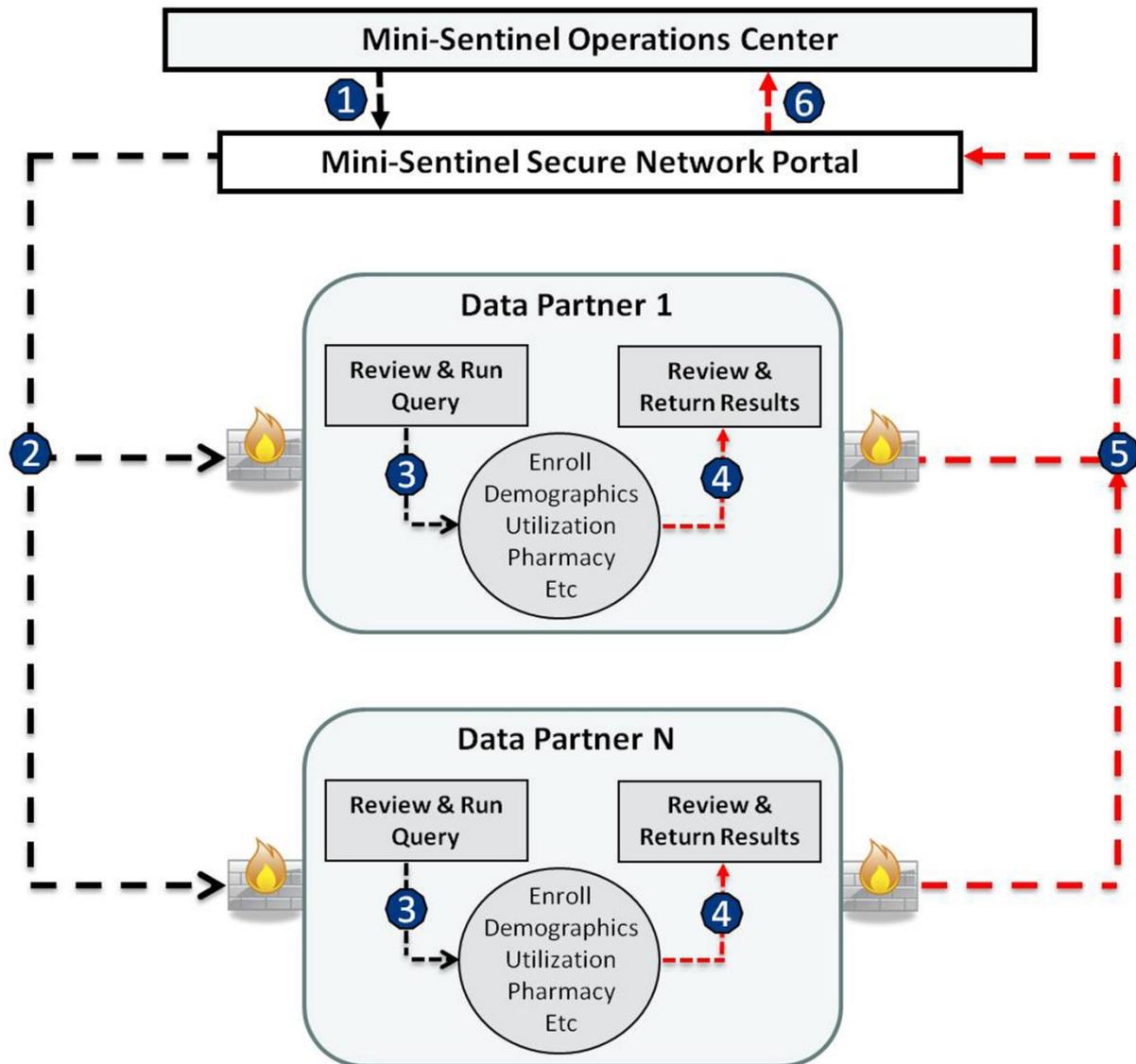
- Connect networks into one Network of Networks
 - Really a Network of Network Data Participants (nodes)
- Create interfaces to engage with network data partners
 - Right partner, right data, right time, right relationship
- Provide an environment for stakeholders to
 - Advertise research capabilities (data and services)
 - Engage in trade of needs and capabilities
 - Publish the resulting knowledge
 - Learn and evolve



Distributed Data / Distributed Analysis

- Data partners keep and analyze their own data
- Standardize the data using a common data model
- Distribute code to partners for local execution
- Provide results, not data, to requestor
- All activities audited and secure

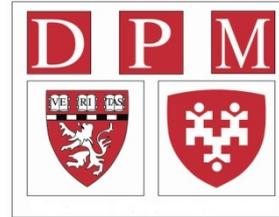
Distributed Analysis



- 1- User creates and submits query (a computer program)
- 2- Data partners retrieve query
- 3- Data partners review and run query against their local data
- 4- Data partners review results
- 5- Data partners return results via secure network
- 6 Results are aggregated

Mini-Sentinel Partner Organizations

Lead – HPHC Institute



Data and scientific partners



Scientific partners



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ORIGINAL ARTICLE

Intussusception Risk after Rotavirus Vaccination in U.S. Infants

W. Katherine Yih, Ph.D., M.P.H., Tracy A. Lieu, M.D., M.P.H., Martin Kulldorff, Ph.D.,
David Martin, M.D., M.P.H., Cheryl N. McMahon-Walraven, M.S.W., Ph.D.,
Richard Platt, M.D., Nandini Selvam, Ph.D., M.P.H., Mano Selvan, Ph.D.,
Grace M. Lee, M.D., M.P.H., and Michael Nguyen, M.D.



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Perspective

Dabigatran and Postmarketing Reports of Bleeding

Mary Ross Southworth, Pharm.D., Marsha E. Reichman, Ph.D., and Ellis F. Unger, M.D.

“In the months following the approval of the oral anticoagulant dabigatran ... in October, 2010, the FDA received through the FDA Adverse Event Reporting System many reports of serious and fatal bleeding events associated with use of the drug.”

ONLINE FIRST

Comparative Risk for Angioedema Associated With the Use of Drugs That Target the Renin-Angiotensin-Aldosterone System

Sengwee Toh, ScD; Marsha E. Reichman, PhD; Monika Houstoun, PharmD; Mary Ross Southworth, PharmD; Xiao Ding, PhD; Adrian F. Hernandez, MD; Mark Levenson, PhD; Lingling Li, PhD; Carolyn McCloskey, MD, MPH; Azadeh Shoaibi, MS, MHS; Eileen Wu, PharmD; Gwen Zornberg, MD, MS, ScD; Sean Hennessy, PharmD, PhD

- Used data for 3.9 million new users of anti-hypertensives in 18 organizations
- Propensity score matched analysis
- No person-level data was shared
- **Five months and \$250,000 required for programming and analysis – compared to 1-2 years and \$2 million without analysis-ready distributed dataset**

ONLINE FIRST

Comparative Risk for Angioedema

Associated With the Use of Drugs That Target

Can we reduce the effort, time, and cost?

Sengwee Toh, ScD; Marsha E. Reichman, PhD; Monika Houstoun, PharmD; Mary Ross Southworth, PharmD; Xiao Ding, PhD; Adrian F. Hernandez, MD; Mark Levenson, PhD; Lingling Li, PhD; Carolyn McCloskey, MD, MPH; Azadeh Shoaibi, MS, MHS; Eileen Wu, PharmD; Gwen Zornberg, MD, MS, ScD; Sean Hennessy, PharmD, PhD

Yes, we can now do this in days or weeks
as part of routine capability

- No person-level data was shared
- Five months and \$250,000 required for programming and analysis – compared to 1-2 years and \$2 million without analysis-ready distributed dataset

Impact / Dissemination

- 4 FDA drug safety communications
 - Tri-valent inactivated flu vaccine and febrile seizures (no increased risk)
 - Rotarix and intussusception (label change)
 - Dabigatran and bleeding (no increased risk)
 - Olmesartan and sprue-like enteropathy (label change)
- 70 peer-reviewed articles
- 48 methods reports / white papers
- Thousands of unique queries and comparisons contributing to over 140 formal assessments

www.mini-sentinel.org

Key Contributors to Mini-Sentinel's Progress

- **Tightly Coupled network**
- **Frequent and coordinated interactions between FDA, data partners, content experts, epidemiologists, and statisticians**
- Clear ownership and goals
- Established agreements and contracts
- Distributed data network (no central repository)
- Public health practice
- Focused on best understood and useful data for purpose
 - First: Claims and administrative data, plus access to full text records
 - Syntax and semantics are clear and understood
 - Then: electronic medical records, registries, ...
 - Much more complex to understand, standardize, and use for research
- Rapid cycle development of capabilities

Core Opportunities

- Learning Health System envisioned as a **loosely coupled network**
- Goal is enhanced data liquidity that can generate VALID results
- Different opportunities for **intra-institutional** versus **inter-institutional learning**

- Intra: How do we encourage creation of learning systems within institutions?
 - Hospitals, payers, providers
- Inter: How do we leverage ongoing work to create a network of network data that enables rapid and efficient data analysis?
 - Across institutions that are already engaged
 - Within and across National boundaries

Intra-Institutional Learning

- All data are available within system (inside a firewall)
- System wants to learn (eg, pragmatic trials)
- Core issues are data syntax, semantics, and liquidity
- Learnings limited to activities observed within system
- Examples - Approaches to:
 - Manage MRSA within the ICU and across hospitals
 - Reduce medication errors, improve vaccination rates
 - Reduce inappropriate procedures
- Intra-institutional learning systems most viable 1st step
- **Core Opportunities**
 - Create willingness (“Learning Health System” accreditation?)
 - Timely and trusted data analytics and responsiveness (unprecedented volume and flow of information)
 - How to effectively share learning

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ESTABLISHED IN 1812

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Targeted versus Universal Decolonization to Prevent ICU Infection

Susan S. Huang, M.D., M.P.H., Edward Septimus, M.D., Ken Kleinman, Sc.D., Julia Moody, M.S., Jason Hickok, M.B.A., R.N., Taliser R. Avery, M.S., Julie Lankiewicz, M.P.H., Adrijana Gombosev, B.S., Leah Terpstra, B.A., Fallon Hartford, M.S., Mary K. Hayden, M.D., John A. Jernigan, M.D., Robert A. Weinstein, M.D., Victoria J. Fraser, M.D., Katherine Haffenreffer, B.S., Eric Cui, B.S., Rebecca E. Kaganov, B.A., Karen Lolans, B.S., Jonathan B. Perlin, M.D., Ph.D., and Richard Platt, M.D., for the CDC Prevention Epicenters Program and the AHRQ DECIDE Network and Healthcare-Associated Infections Program*

METHODS

We conducted a pragmatic, cluster-randomized trial. Hospitals were randomly assigned to one of three strategies, with all adult ICUs in a given hospital assigned to the same strategy.

CONCLUSIONS

In routine ICU practice, universal decolonization was more effective than targeted decolonization or screening and isolation in reducing rates of MRSA clinical isolates and bloodstream infection from any pathogen.

Inter-Institutional Learning

- Data held across institutions introduces additional complexities for enabling a **loosely-coupled LHS**
- Need ways to communicate information about every request for use of data so others can efficiently evaluate the request and respond (query APIs)
 - Query description
 - Intended use
 - Data requirements
 - Response description
- **Core Opportunity: Enable machine-readable distributed queries**
 - Taxonomy, meta-data, etc to enable automation of the research and learning process
 - Marketplace to encourage participation, costs are real and benefits diffuse
 - Look to other industries that share information but not raw data for benefit of all

Example

Re-hospitalization rate for knee replacement surgeries

- **Query Description:** Matched cohort design to assess the rate of re-hospitalization 1-183 days post-discharge
- **Intended use:** 1) Stratified rates of re-hospitalization and a propensity-score matched study comparing different surgical approaches; results will be published
- **Data needed:** Longitudinal capture of inpatient, outpatient, and pharmacy data for 12 months before and 6 months after surgery
- **Data returned:** Person-level file with indicators for all study-defined characteristics
- **Data aggregation:** Data will be aggregated across contributing institutions

What would be helpful for my work

- Querying taxonomy and metadata
- Health data metadata
- Better ways to
 - Translate queries across data sources, models, types
 - Translate data into common model
- Better understanding of patient identification risks and how they relate to specific LHS approaches
 - Ninja defense

Lessons

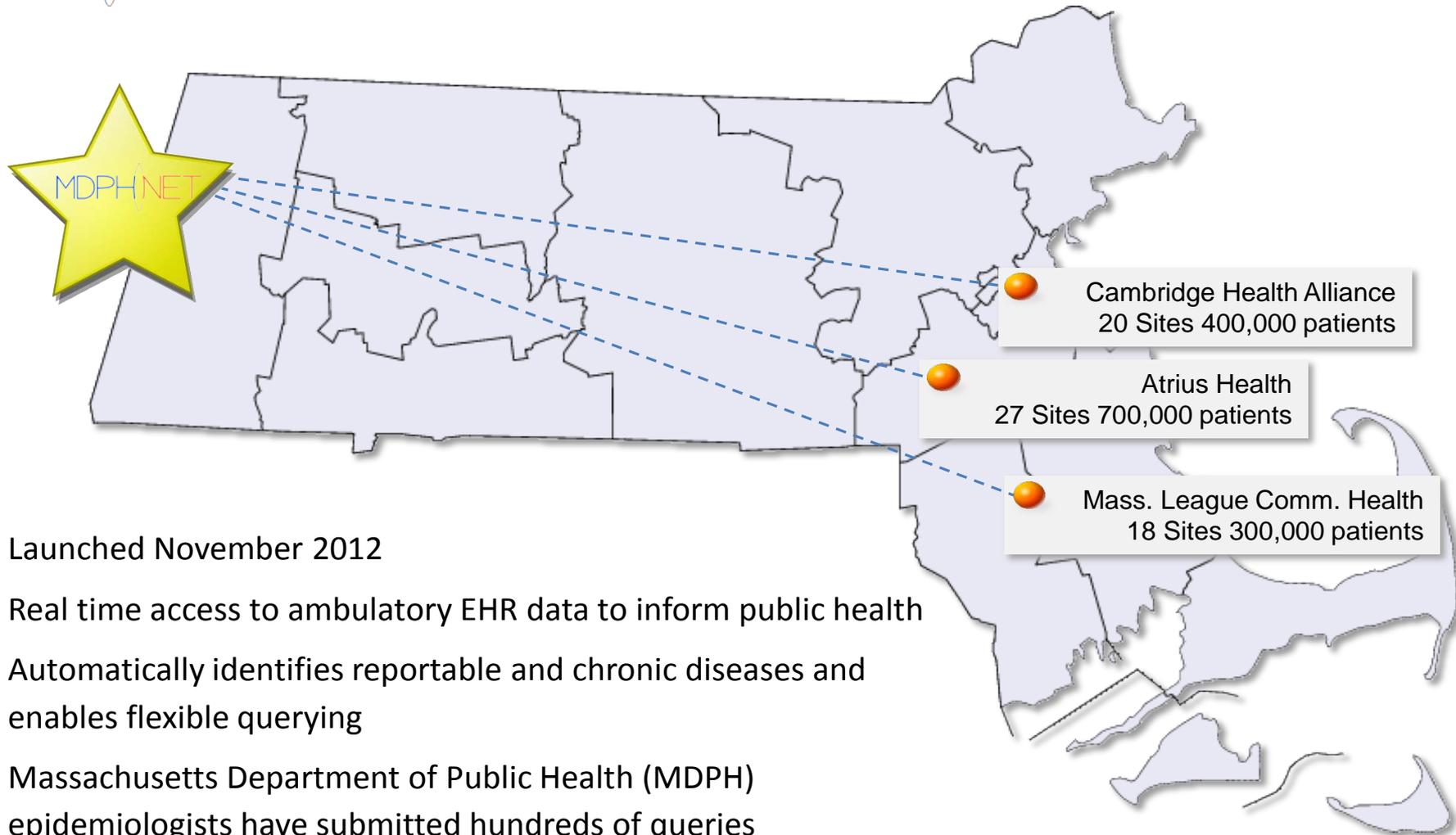
- What I typically ignore
 - Ontology mapping and “standardized” phenotyping efforts
 - Promises about data standards and how things are just about to get better
- Medicine is local and driven by payment (just in US?)
 - System designed for payment, not documentation of health status
 - Providers document well what is needed for payment
 - Investments made to lower cost, generate revenue, or otherwise improve local performance
- Policy levers (waiting for the world to turn rational is not a winning strategy)
 - Finance
 - Regulation
 - **Patients: Will patients demand change and are they will to pay for it?**

Conclusions

- Find opportunities to succeed by solving clear and small problems
 - Infections control in hospitals
 - Influenza surveillance
- Remember the healthcare levers
- Look for the place where all actors gain
 - Messaging clearinghouse (validate HL7, XML message against a standard)
 - Population health and public health
 - Institutions do not want to share data, but will share information
 - Invoke patient demand for improvement
- Create the facts on the ground

Thank you!

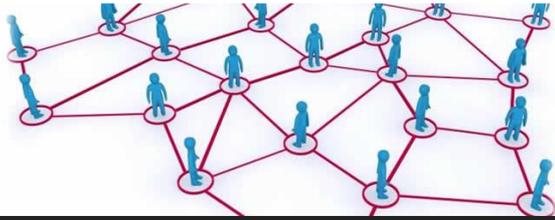
MDPH NET: Real Time Public Health Surveillance



- Launched November 2012
- Real time access to ambulatory EHR data to inform public health
- Automatically identifies reportable and chronic diseases and enables flexible querying
- Massachusetts Department of Public Health (MDPH) epidemiologists have submitted hundreds of queries
- Now an operational suite of systems supported by MDPH

For More Information

PopMedNet Website popmednet.org



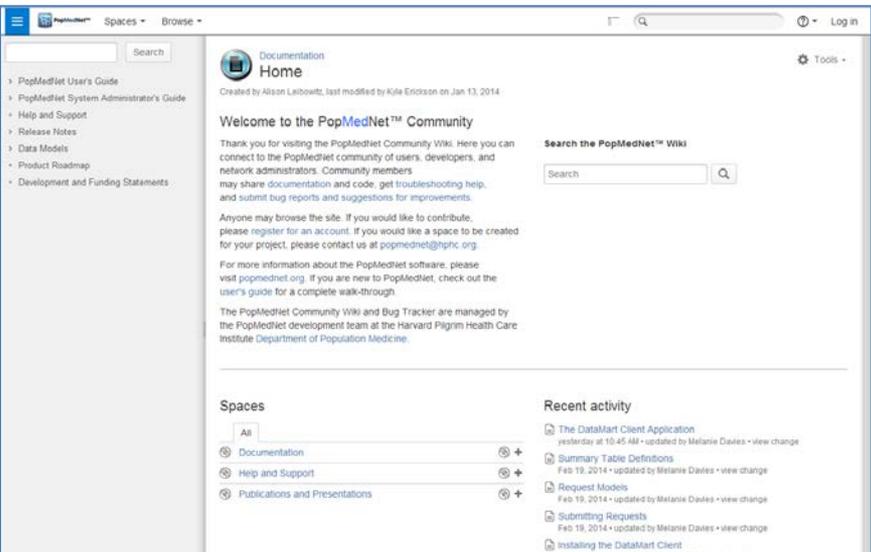
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PopMedNet

The PopMedNet™ software application enables simple creation, operation, and governance of distributed health data networks. It facilitates distributed analyses of electronic health data to support medical product safety, comparative effectiveness, quality, medical resource use, cost-effectiveness, and related studies. The software:

- Allows users to send questions to the data
- Provides secure, customized, private portals, and file transfer capabilities that allow users to query data held by disparate partners
- Allows participating network data partners to maintain physical and operational control over their data
- Supports both menu-driven analyses and distribution of complex analytic programs

PopMedNet Wiki popmednet.atlassian.net/wiki



Documentation Home
Created by Alison Leibowitz, last modified by Kyle Erickson on Jan 13, 2014

Welcome to the PopMedNet™ Community

Thank you for visiting the PopMedNet Community Wiki. Here you can connect to the PopMedNet community of users, developers, and network administrators. Community members may share documentation and code, get troubleshooting help, and submit bug reports and suggestions for improvements.

Anyone may browse the site. If you would like to contribute, please register for an account. If you would like a space to be created for your project, please contact us at popmednet@hphc.org.

For more information about the PopMedNet software, please visit popmednet.org. If you are new to PopMedNet, check out the user's guide for a complete walk-through.

The PopMedNet Community Wiki and Bug Tracker are managed by the PopMedNet development team at the Harvard Pilgrim Health Care Institute Department of Population Medicine.

Search the PopMedNet™ Wiki

Spaces

- All
- Documentation
- Help and Support
- Publications and Presentations

Recent activity

- The DataMart Client Application
yesterday at 10:45 AM • updated by Melanie Davies • view change
- Summary Table Definitions
Feb 19, 2014 • updated by Melanie Davies • view change
- Request Models
Feb 19, 2014 • updated by Melanie Davies • view change
- Submitting Requests
Feb 19, 2014 • updated by Melanie Davies • view change
- Installing the DataMart Client

Thank You

Links

- www.PopMedNet.org
- mehi.masstech.org/what-we-do/hie/mdphnet/about
- www.pcornet.org
- www.mini-sentinel.org
- nihcollaboratory.org/Pages/distributed-research-network.aspx

NIH Collaboratory Distributed Research Network Presentations

<https://www.nihcollaboratory.org/Pages/Grand-Rounds-03-15-13.aspx>

<https://www.nihcollaboratory.org/Pages/Grand-Rounds-09-13-13.aspx>

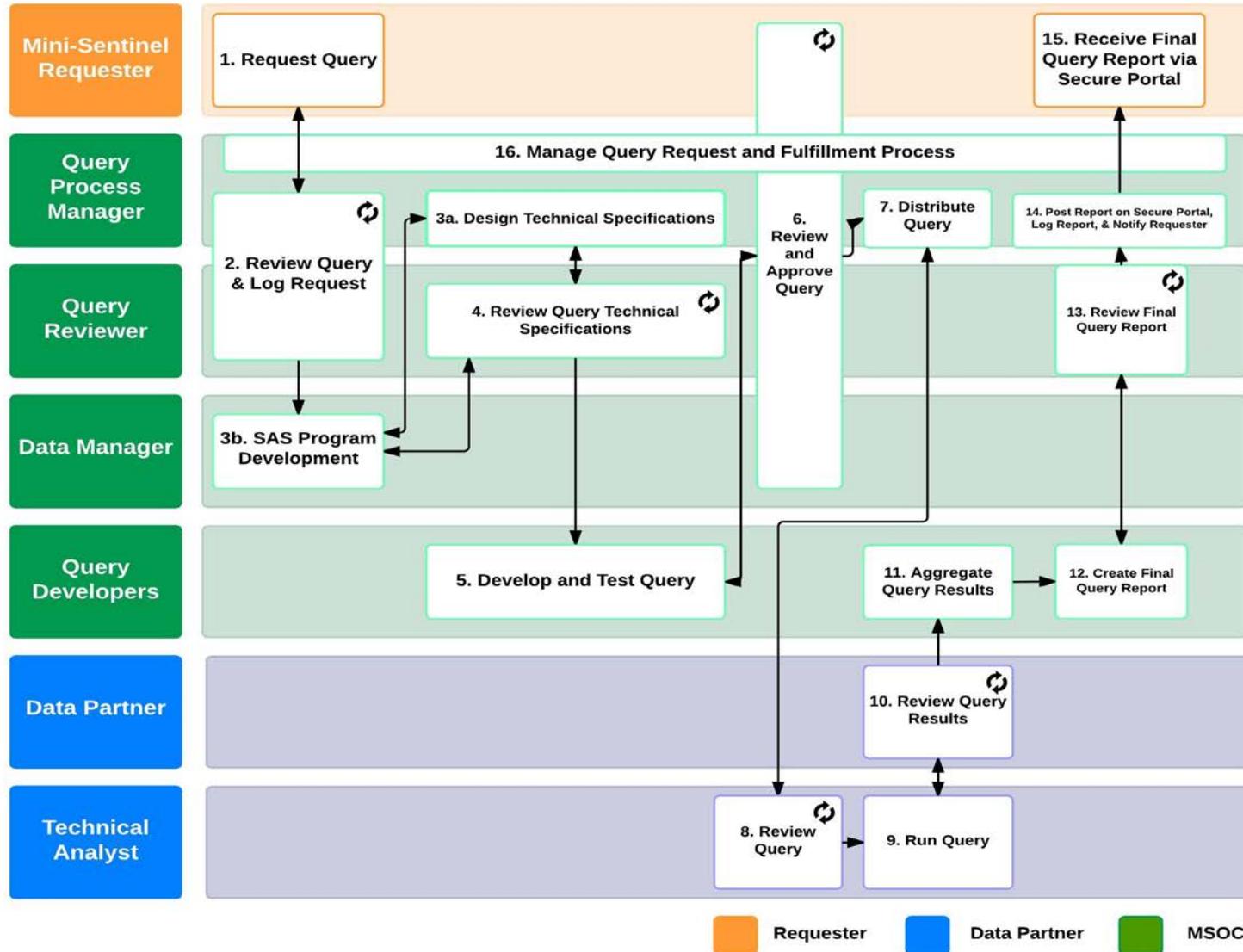
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Mini-Sentinel Query Fulfillment Process





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Mini-Sentinel and Regulatory Science — Big Data Rendered Fit and Functional

Bruce M. Psaty, M.D., Ph.D., and Alasdair M. Breckenridge, M.D.

In medicine, “big data” come in many forms. With the financial incentives provided by Medicare and Medicaid for the “meaningful

functions of billing and clinical care. If, as Nate Silver suggests in *The Signal and the Noise*, “Most of the increasing quantity of infor

“The Mini-Sentinel ’ provides an essential public health service. The current configuration — the data model, the methods development, and the investigative team — represents an impressive achievement..

ciation studies funded by the National Heart, Lung, and Blood Institute have produced data sets with millions of genetic variants for each participant, encouraged the development of consortia with hundreds of thousands of study participants, and resulted in discoveries about the genetic origins

create systems of study settings that can contribute meaningfully to the health of the public.

One model is the Mini-Sentinel. A pilot project of the Sentinel Initiative of the Food and Drug Administration (FDA), the Mini-Sentinel has created a nationwide system that uses electronic data