

HIMSS



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opportunity is here

HIMSS Life Sciences Roundtable

November 16, 2011

transforming healthcare through IT™

Agenda



Welcome

Call to Order (Shelley Price)

Introduction

HIMSS Life Sciences Roundtable -- Scope and Vision (Shelley Price, Stefanie Bednarczyk)

Topic discussion

Advancing the Science of Observational Data Analysis in Life Sciences (J. Marc Overhage, OMOP)

Wrap-Up

(Shelley Price)

Adjournment



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HIMSS Mission

HIMSS frames and leads healthcare practices and public policy through its content expertise, professional development, and research initiatives designed to promote information and management systems' contributions to improving the quality, safety, access, and cost-effectiveness of patient care.

HIMSS Life Sciences Roundtable *Cause*

Advance efforts to capture, share, aggregate, and utilize health data through health IT that will further advances in life sciences innovation resulting in improved patient care and health outcomes.

Life Sciences Roundtable Leadership & Contact Information

Chairperson:

Stefanie Bednarczyk

Life Sciences Account Executive

Health Solutions Business Unit

SAIC

STEFANIE.M.BEDNARCZYK@saic.com

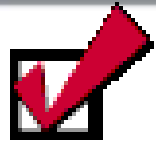
HIMSS Staff Liaison:

Shelley Price

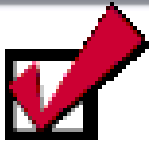
Director, Payer and Life Sciences

HIMSS

sprice@himss.org



LS Roundtable FY12 Goals



- a) **Educate, share knowledge, and foster collaboration:** Inform the life sciences industry on emerging health IT policies and activities, engage on relevant issues with industry experts, and partner to support the cause
- Hold monthly roundtable meetings with relevant speakers to support the learning and sharing of knowledge, issues, and opportunities
 - Create fact sheets, case studies, white papers documenting current life sciences engagement with and advancements using health IT
 - Serve as a conduit for sharing and collaborating between external partners and life sciences
- b) **Engagement and integration:** Support HIMSS as multi-stakeholder, authoritative voice by adding to the knowledgebase and advancing the engagement of life sciences stakeholders within HIMSS
- Incorporate the life sciences perspective into HIMSS' policy recommendations and activities
 - Provide views to and feedback on HIMSS responses to Federal regulatory comment periods and legislation
 - Provide input into public policy agenda-setting exercises



LS Roundtable FY12 Topics



Topics may include

- Comparative effective research
 - Connecting patient care and biomedical research through data sharing
- Personalized medicine
- Interoperability of research databases for data analytics and mining
- Clinical trials
 - Data analytics
 - Integration of electronic health records into electronic data capture systems
- Health regulatory affairs issues impacting the Life Sciences sector

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**OBSERVATIONAL
MEDICAL
OUTCOMES
PARTNERSHIP**

**Advancing the Science of
Observational Data Analysis in Life
Sciences**

November 16, 2011

J. Marc Overhage, MD, PhD



Observational Medical Outcomes Partnership

- ***Public-Private Research Partnership established to inform the appropriate use of observational healthcare databases for studying the effects of medical products:***
 - Conducting methodological research to empirically evaluate the performance of alternative methods on their ability to identify true associations
 - Developing tools and capabilities for transforming, characterizing, and analyzing disparate data sources across the health care delivery spectrum
 - Establishing a shared resource so that the broader research community can collaboratively advance the science

Governance

Executive Board - Oversees Partnership Operations

- Janet Woodcock, MD - FDA
- Rebecca Burkholder -The National Consumers League
- Sherine Gabriel, MD, MSc - The Mayo Clinic
- Cynthia Gilman, JD - Henry Jackson Foundation
- Jesse L. Goodman, MD, MPH – FDA
- Stephen Jacobsen, MD, PhD - Southern California Permanente Medical Group
- Ronald L. Krall, MD - Retired GSK
- Richard Platt, MD, MSc - Harvard Medical School and Harvard Pilgrim Health Care
- Brian Strom, MD, MPH - Pennsylvania School of Medicine
- David Wheadon, MD - PhRMA
- Marcus Wilson, Pharm.D. - Healthcore

Scientific Advisory Board - independent review of and expert input into the scientific aspects of OMOP's activities

- Elizabeth Andrews, RTI Health Solutions
- Andrew Bate, Pfizer
- Jesse Berlin, Johnson & Johnson
- Robert Davis, Kaiser Permanente
- Sean Hennessy, University of Pennsylvania
- Mike Katz, FDA patient representative
- Allen Mitchell, Boston University
- David Page, University of Wisconsin
- Ken Rothman, RTI Health Solutions
- Judy Racoosin, FDA
- Judy Staffa, FDA

Healthcare Informatics Advisory Board - independent review and expert input into the technology, privacy, data model, and terminology

- Col. Kevin Abbott
- Jeff Brown, Harvard Medical School
- Stan Huff, Intermountain Healthcare
- Diane MacKinnon, IBM (retired)
- Ken Mandl, Harvard University
- Clem McDonald, National Library of Medicine
- Mitra Rocca, FDA
- Rob Thwaites, United BioSource Corporation

Timeline

First 2-year Program

- Q4 2008
 - Research plan approved
 - Budget finalized and funding secured
- Q3 2009
 - Central Data Infrastructure operational
 - Methods Collaborations launched
 - Distributed Partners Collaborations launched
- Q1 2010
 - Distributed Partners operational
 - Data characterization complete
 - Methods feasibility complete
- Q3 2010
 - Initial methods experiments completed
- Q1 2011
 - Analysis complete
 - Results previewed at OMOP Symposium
 - Distributed Partners Reports complete

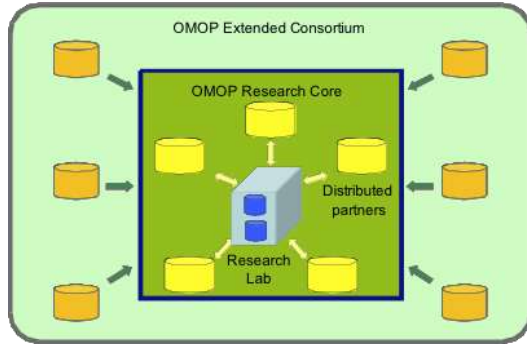
Current Program

- Q2 2011
 - Ongoing analysis of results
 - 2011 Research Plan Approved
 - Additional methods collaborations launched
 - Additional Test Cases defined
 - Central data sets refreshed
 - New simulated data sets generated
- Q3 2011
 - Experiments in simulated data underway (Q4 target completion)
 - Experiments in observational data underway (Q1 2012 target completion)
 - Collaborations launched to extend Data Model for three AHRQ networks
 - Collaboration launched to extend OMOP into the EU-ADR network

OBJECTIVES for Original Two Year Program

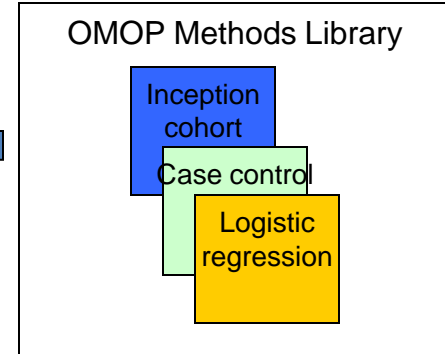
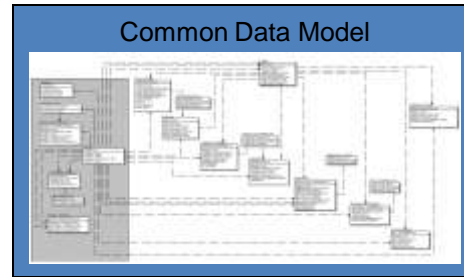
- **Define and test a pool of analytical methods** that can be used to explore the relationships between drugs and health-related conditions across multiple types of observational data (administrative claims, inpatient and outpatient EHRs).
- **Develop and test methods** to apply to a network of central and distributed data sources for drug safety and effectiveness questions
- **Assess the performance of the analytical methods**
- Based on the results of these analyses, determine **how the results can shape the implementation** of an active drug surveillance program.

Approach for Original Two Year Program



- 10 data sources
- Claims and EHRs
- 170M+ lives
- Simulated data (OSIM)

- Open-source
- Standards-based
- Systematic data characterization and quality assurance



- 14 methods implemented as standardized procedures
- Full transparency with open-source code and documentation
- Epidemiology, statistical and machine learning designs



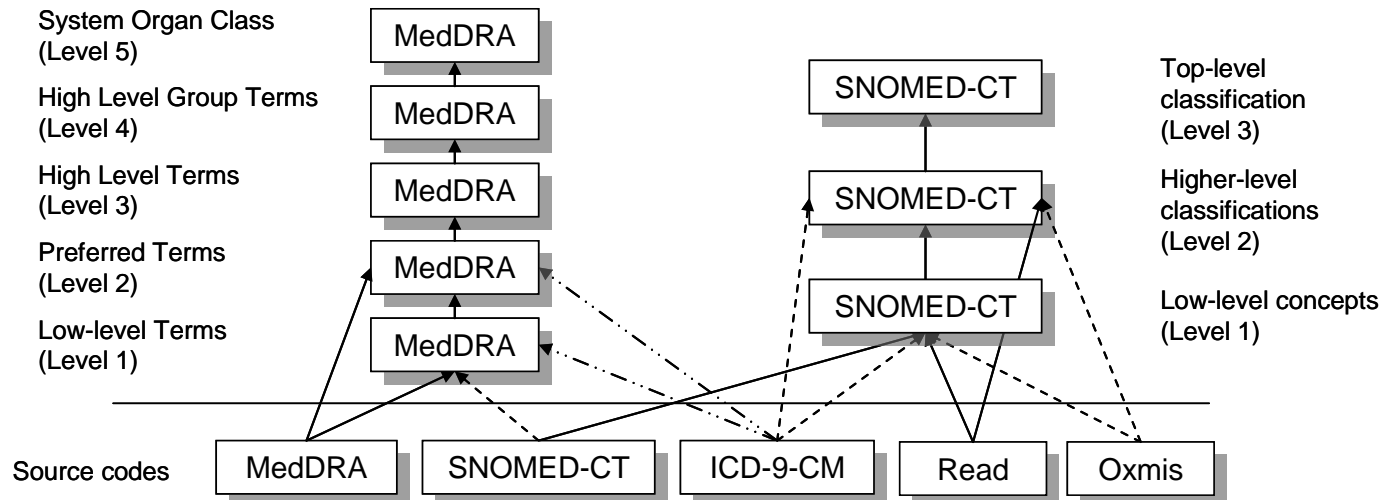
Outcome	ACE Inhibitors	Amphotericin B	Antibiotics: erythromycins, sulfonamides, tetracyclines	Antiepileptics: carbamazepine, phenytoin	Benzodiazepines	Beta blockers	Bisphosphonates: alendronate	Tricyclic antidepressants	Typical antipsychotics	Warfarin
Angioedema	Red	Blue	White	Blue	Blue	White	White	White	White	Blue
Aplastic Anemia	Blue	Blue	White	Red	Blue	White	White	Blue	White	Blue
Acute Liver Injury	White	Blue	Red	White	Blue	White	White	Blue	White	White
Bleeding	White	White	Blue	White	White	White	White	Blue	White	Red
Hip Fracture	Blue	Blue	White	White	Red	Blue	White	White	White	Blue
Hospitalization	Green	White	White	White	White	White	White	White	White	White
Myocardial Infarction	White	Blue	White	Blue	White	White	Blue	Red	Red	White
Mortality after MI	White	Blue	White	Blue	White	Green	White	White	White	Blue
Renal Failure	White	Red	Blue	White	Blue	White	White	Blue	White	Blue
GI Ulcer Hospitalization	Blue	White	White	Blue	White	Blue	Red	White	Blue	White

OMOP Tools and Their Application

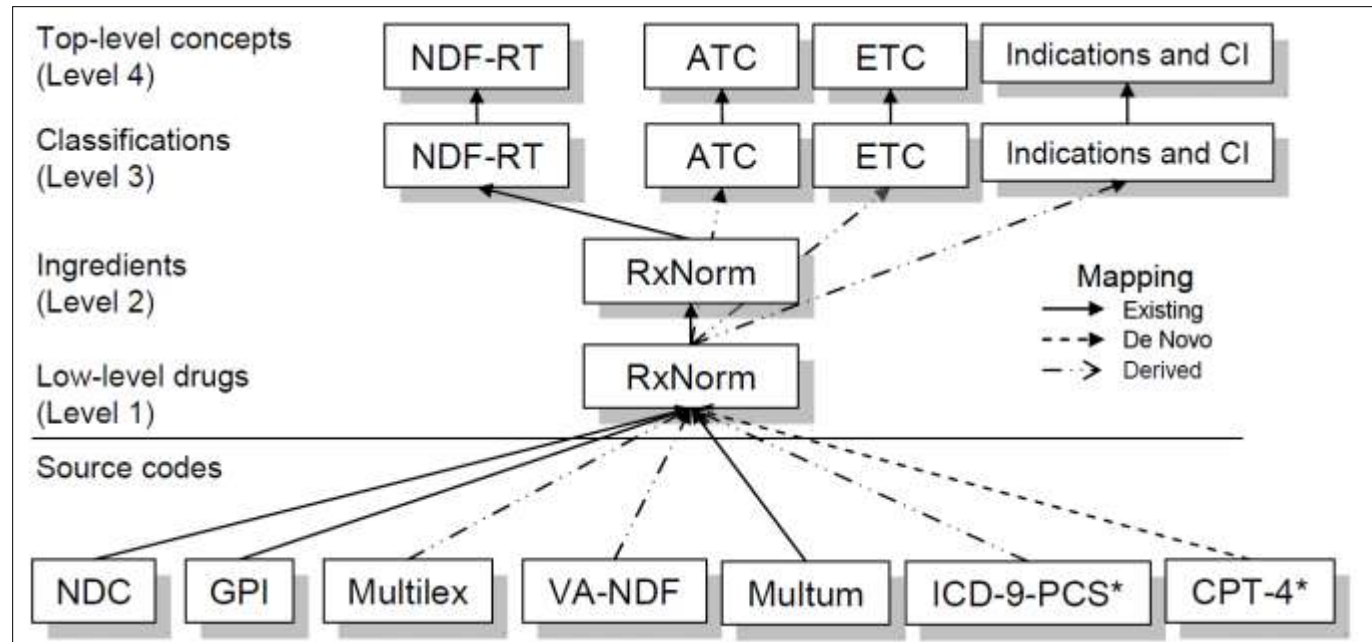
OMOP Tool	Application
Common Data Model (CDM) & Standardized Terminologies	<ul style="list-style-type: none"> • Analytical model to organize disparate types of data into a common format • Conceived for active medical product surveillance, but extensible for other use cases • Optimized for large-scale analytics • Implemented using standardized terminologies
Health Outcomes (Definitions)	<ul style="list-style-type: none"> • An open-source library of 35 HOI definitions for use in observational studies
Methods – Analytics	<ul style="list-style-type: none"> • 14 methods • Epidemiology designs • Statistical approaches adapted for longitudinal data
Observational Medical Dataset Simulator (OSIM)	<ul style="list-style-type: none"> • OSIM generates simulated longitudinal patient records • Models complexities found in real-world healthcare data organized in the OMOP CDM format
Observational Source Characteristics Analysis Report (OSCAR)	<ul style="list-style-type: none"> • Generates summary statistics from observational datasets <ul style="list-style-type: none"> ✓ Validation of transformation from raw data to OMOP common data model ✓ Comparison of overall database to specific subpopulations of interest (such as people exposed to a particular drug or people with a specific condition) ✓ Providing context for interpreting and analyzing findings of drug safety studies

Standardizing terminologies to accommodate disparate observational data sources

Standardizing conditions:



Standardizing drugs:



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Standardized analyses for risk identification

Method Name	Contributor
DISPROPORTIONALITY ANALYSIS	
Disproportionality analysis (DP)	Columbia / Merck
IC Temporal Pattern Discovery (ICTPD)	Uppsala Monitoring Centre
HSIU Cohort Method (HSIU)	Indiana University / Regenstrief Institute
Longitudinal Gamma Poisson Shrinker (LGPS) & Longitudinal Evaluation of Observational Profiles of Adverse events Related to Drugs (LEOPARD)	Erasmus University Medical Center Rotterdam
CASE-BASED METHODS	
Bayesian Multivariate Self-Controlled Case Series (MSCCS)	Columbia University / UCLA
Multi-set Case Control Estimation (MSCCE)	Columbia University / GlaxoSmithKline
Bayesian Logistic Regression (BLR)	Rutgers / Columbia University
Case-control Surveillance (CCS)	Lilly
Case-crossover (CCO)	University of Utah
EXPOSURE-BASED METHODS	
Observational Screening (OS)	ProSanos –UBC / GlaxoSmithKline
High-dimensional Propensity Score (HDPS)	Harvard Medical School / Columbia
Incident User Design (IUD)	University of North Carolina
SEQUENTIAL TESTING METHODS	
Maximized Sequential Probability Ratio Test (MSPRT)	Harvard Pilgrim / Group Health
Conditional Sequential Sampling Procedure (CSSP)	Harvard Pilgrim / Group Health

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OMOP Tools and Their Application (cont)

OMOP Tool	Application
Natural History Analysis (NATHAN)	<ul style="list-style-type: none"> • An extension of OSCAR, where data characteristics can be produced for a particular subpopulation of interest <ul style="list-style-type: none"> ✓ Exposed population (e.g. patients taking antibiotics) ✓ Cases (e.g. patients with acute liver injury) ✓ Exposed cases (e.g. patients taking antibiotics who develop acute liver injury) • Additional NATHAN summary statistics provide context for interpreting and analyzing findings of drug safety studies • Use NATHAN to refine HOI algorithms in active surveillance
Regularized Identification of Cohorts (RICO)	<ul style="list-style-type: none"> • Standardizes patient cohort selection • Patients meeting the criteria can be automatically and rapidly selected from any database conforming to the OMOP CDM
Generalized Review of OSCAR Unified Checking (GROUCH)	<ul style="list-style-type: none"> • Data quality summary report • Produces a report for each data source with warnings of implausible and suspicious data observed from the OSCAR summary • Allows for data quality review of specific drugs (such as the ingredients that comprise the OMOP drugs of interest) or specific conditions

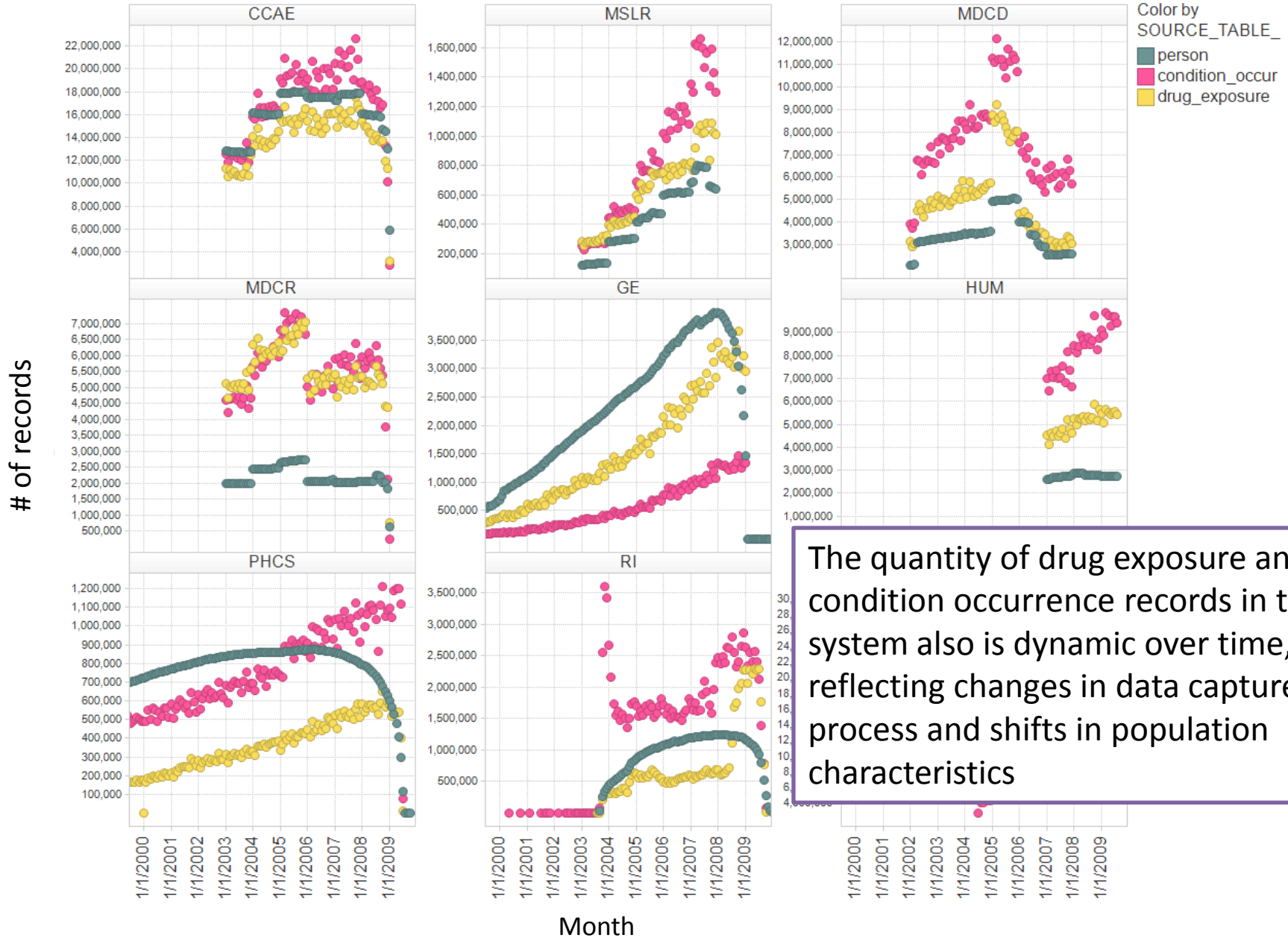
OMOP Data Community

Designed to test Different Data Sources

- Research Laboratory
 - Coordinating Center
 - Five Central Databases
 - GE
 - Thomson Reuters
 - Distributed Partners*
 - Department of Veterans Affairs
 - Miami-Humana Health Services Research Center
 - Partners Healthcare
 - Regenstrief Institute
 - SDI
- 
- **178 million persons with patient-level data**
 - **5.4 billion drug exposures**
 - **5.8 billion procedures**
 - **2.3 billion clinical observations**

* Funded through Q1 2011

Standardized Records Over Time



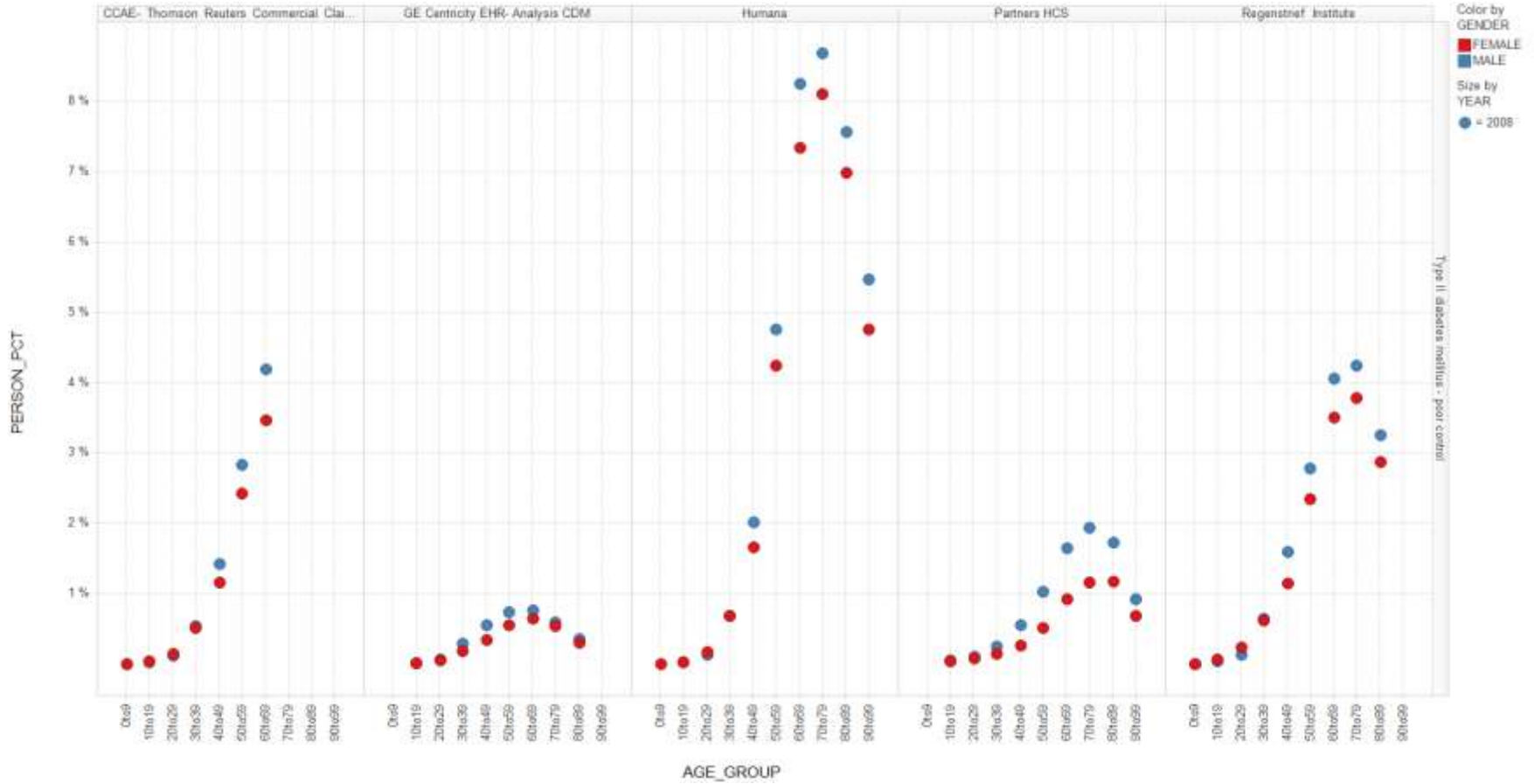
Drilldown into 'Metabolism and nutrition disorders'

Treemap

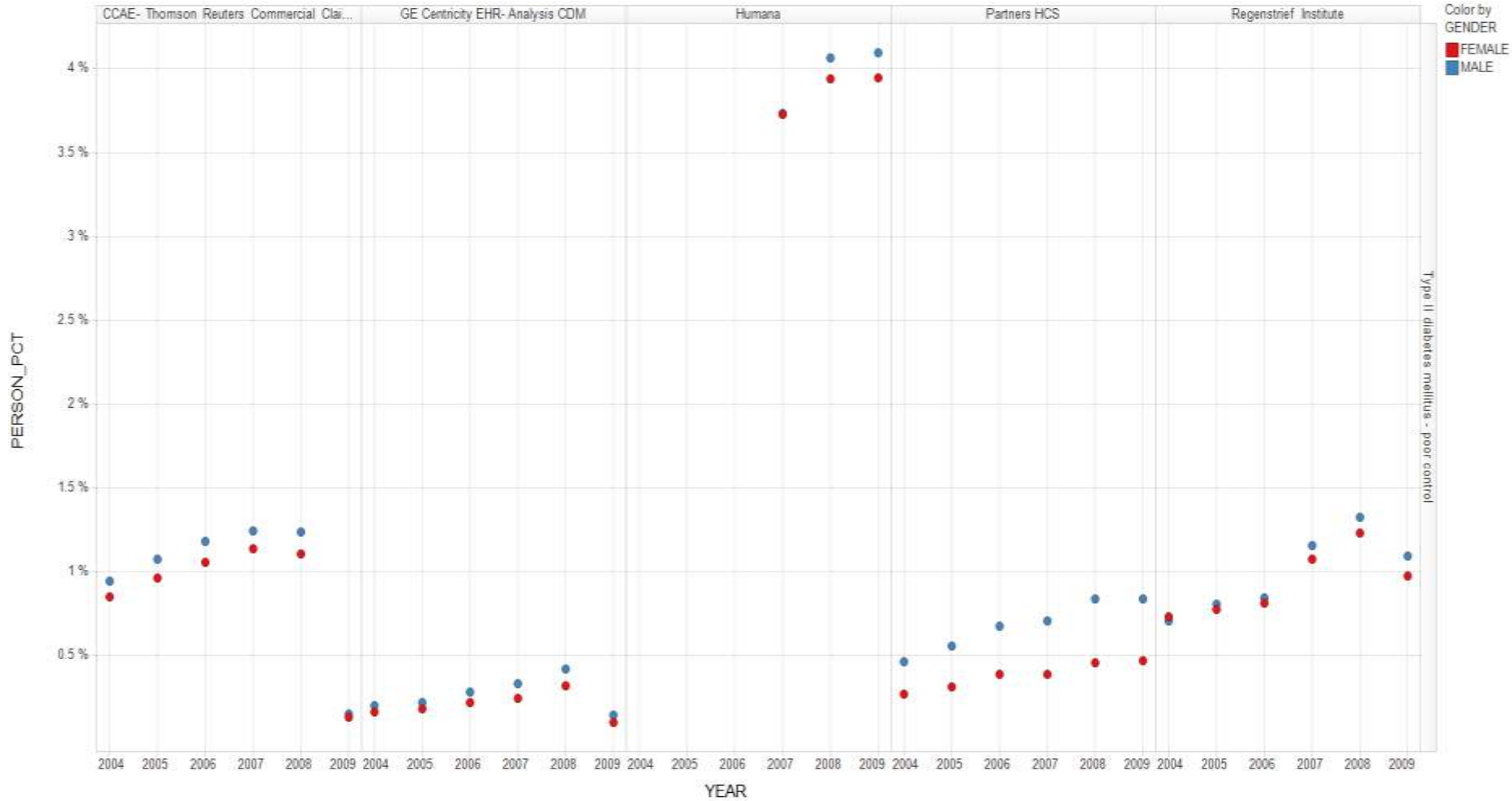


SOURCE_NAME: MDCR- Thomson Reuters Medicare- Analysis CDM
 SOC_CONCEPT_NAME: Metabolism and nutrition disorders
 HLG_T_CONCEPT_NAME: Glucose metabolism disorders (incl diabetes mellitus)
 CONDITION_CONCEPT_NAME: Diabetes mellitus type 2
 STANDARD_PREV: 5.432 %
 RR: 1.33

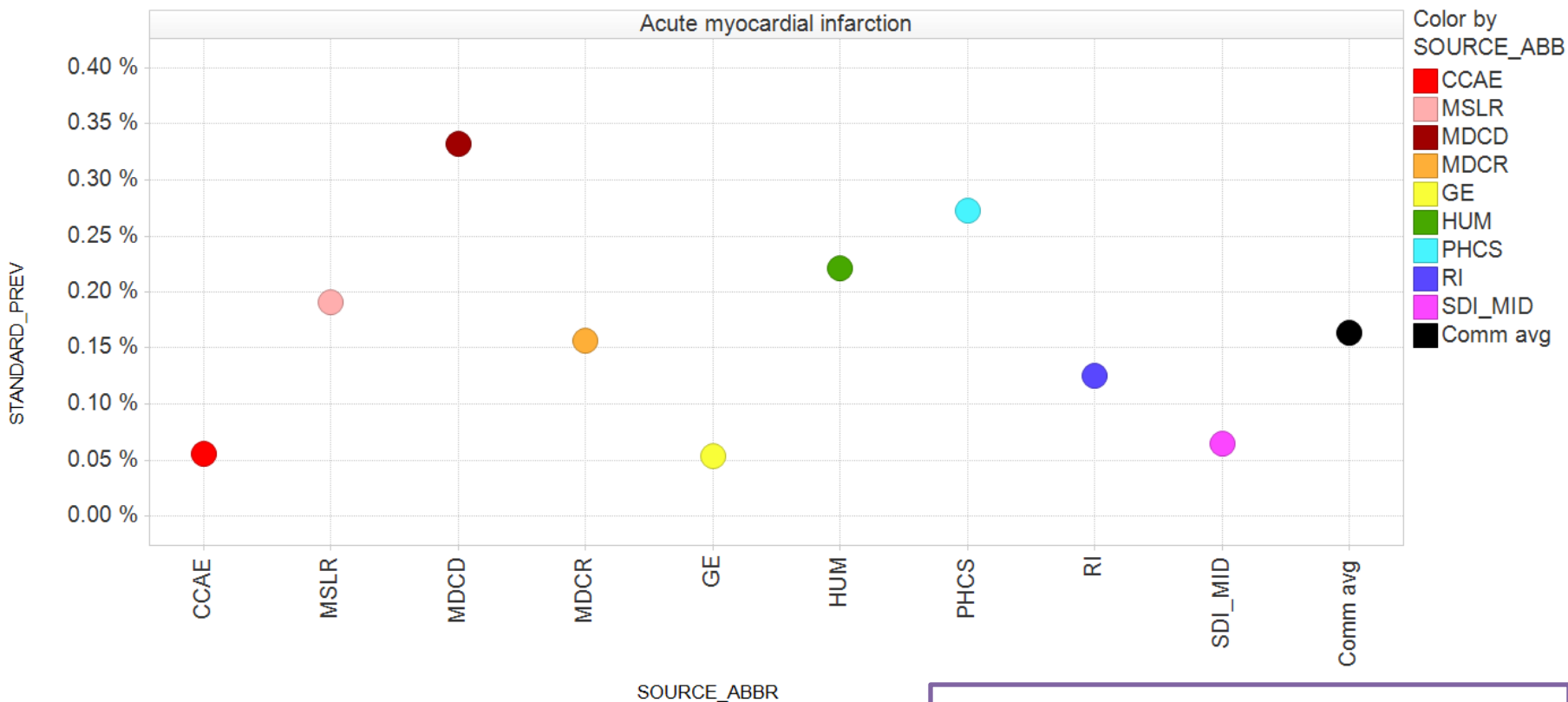
Exploring diabetes across sources



Exploring diabetes across sources



Exploring prevalence of disease: ex: Acute Myocardial Infarction



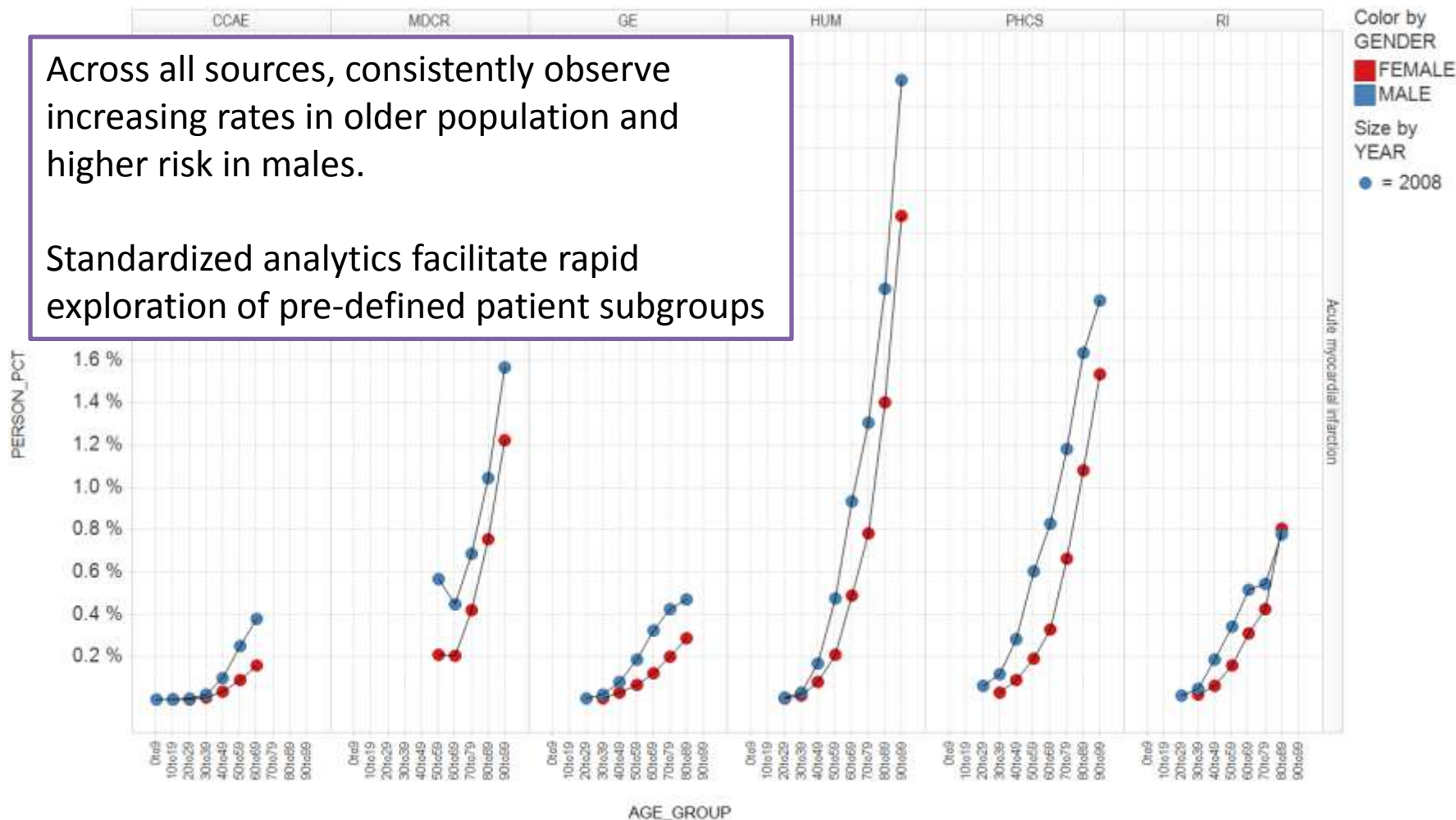
NQMC referent rates from Canada:
0.25% in 2003/4 decreased to
0.22% in 2008/9

Standardized condition prevalence = 5-yr annualized prevalence,
stratified by age and gender, standardized to US Census

Exploring prevalence of disease: ex: Acute Myocardial Infarction

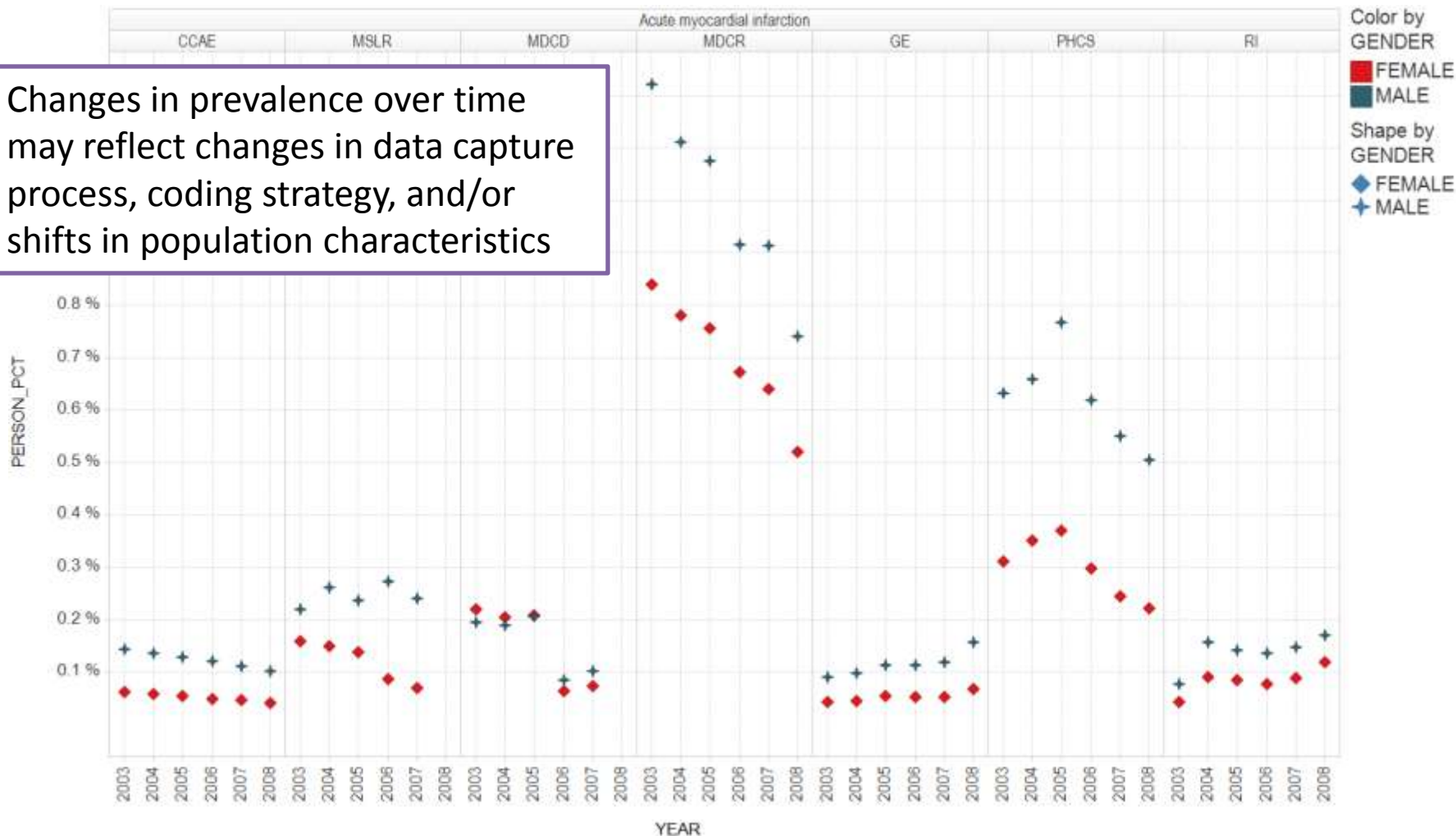
Across all sources, consistently observe increasing rates in older population and higher risk in males.

Standardized analytics facilitate rapid exploration of pre-defined patient subgroups

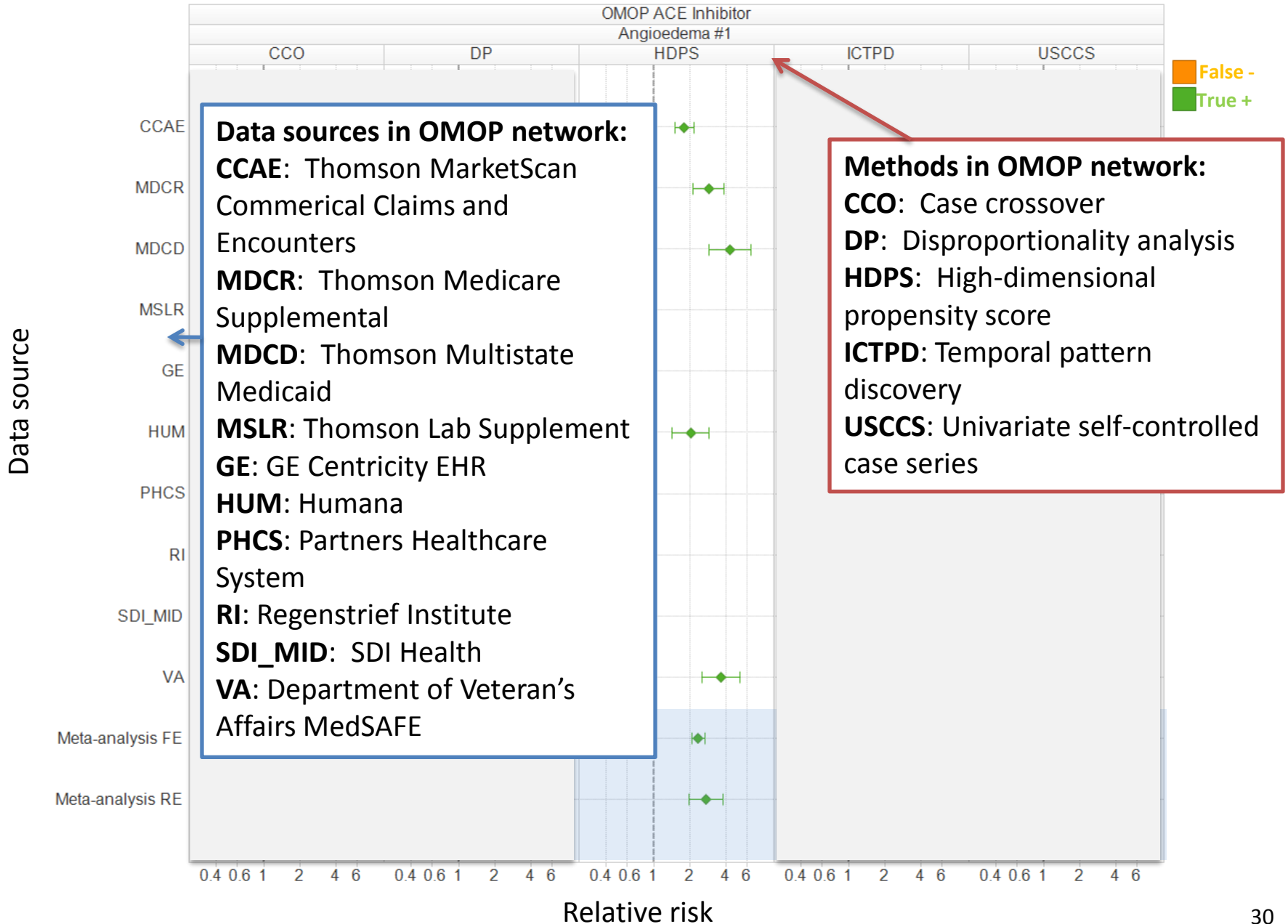


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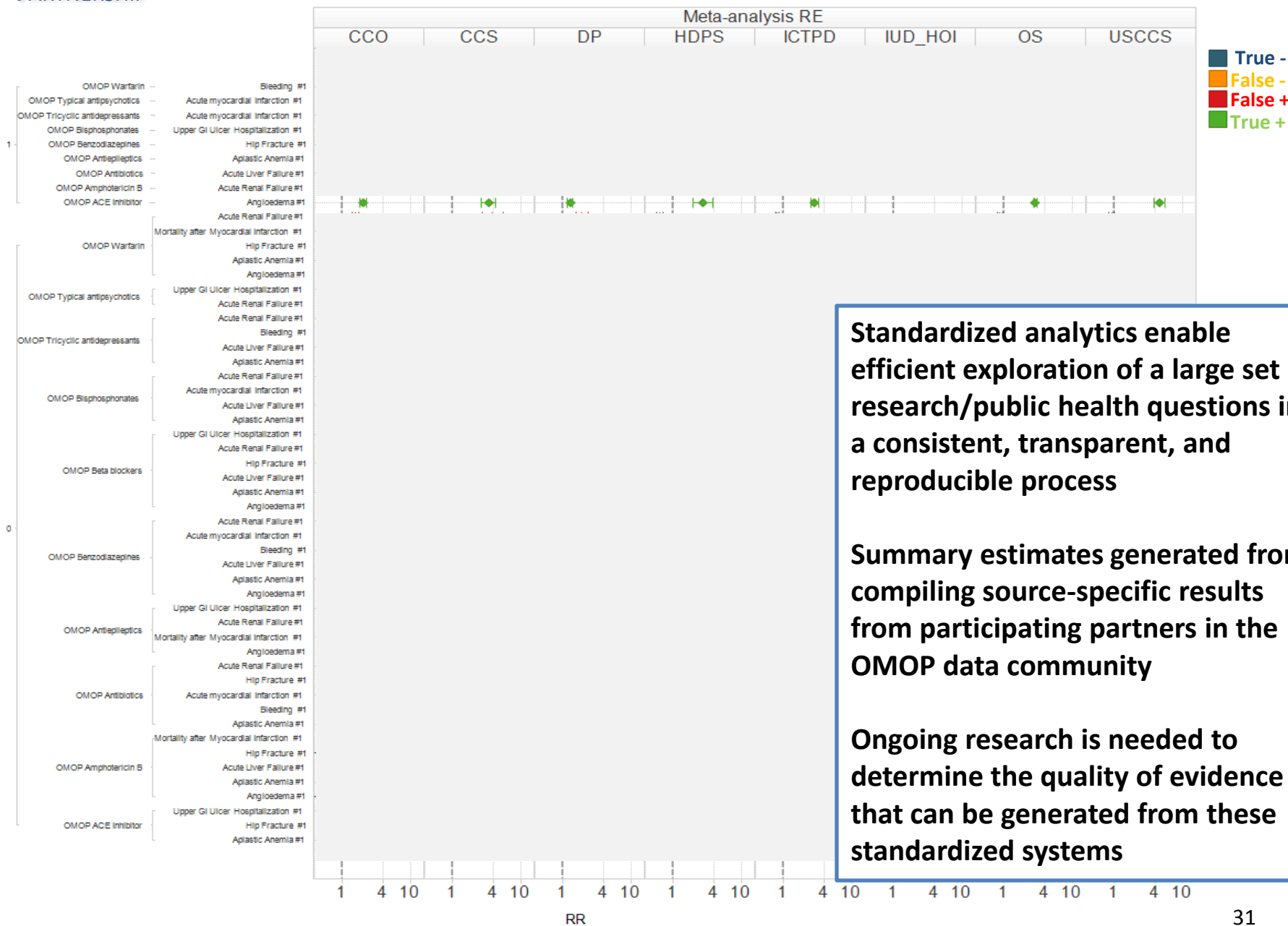
Changes in prevalence over time may reflect changes in data capture process, coding strategy, and/or shifts in population characteristics



Estimating the strength of association between exposure and outcome



Distribution of estimates across all drug-outcome pairs

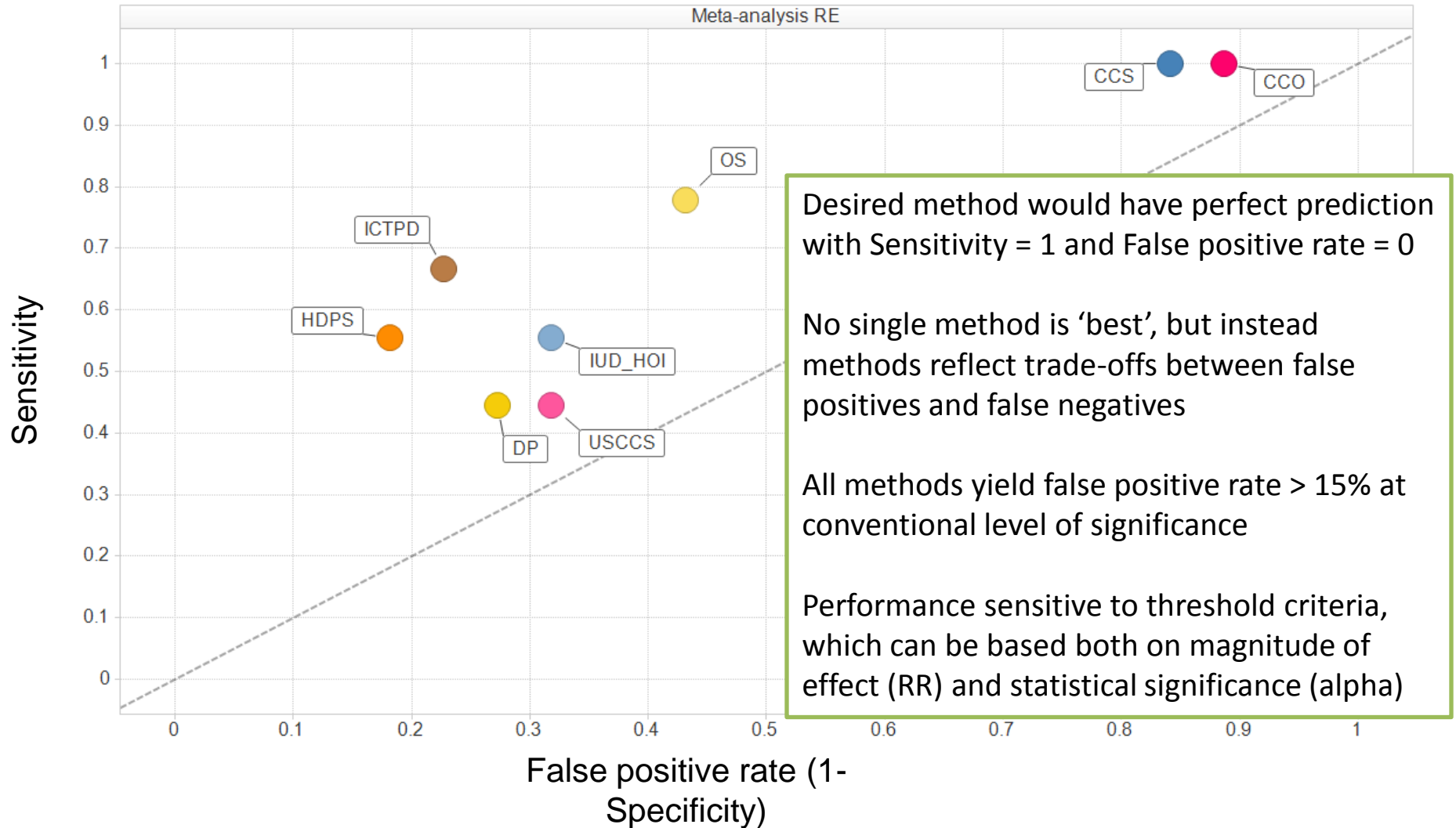


Standardized analytics enable efficient exploration of a large set of research/public health questions in a consistent, transparent, and reproducible process

Summary estimates generated from compiling source-specific results from participating partners in the OMOP data community

Ongoing research is needed to determine the quality of evidence that can be generated from these standardized systems

Comparing methods by sensitivity and specificity at alpha=0.05



Summary for Original Two Year Program

- A risk identification system can complement current practice by providing evidence to support a comprehensive safety assessment
- No one clear 'best' method, as it depends on tolerance for false positives vs. false negatives
- In this experiment, active surveillance methods achieved:
 - At 50% sensitivity, false positive rate ranges 16%-30%
 - At 10% false positive rate, sensitivity ranges 9%-33%
- Need to be cautious in interpreting results from single method in single database
 - Replication does not necessarily provide complete confidence
- ***Further empirical research needed to have more complete understanding of operating characteristics before widespread adoption (Current year 3)***

OMOP 2011/2012 Research Agenda

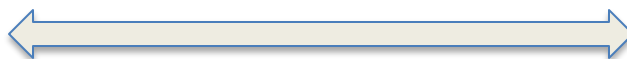
Drug-outcome pairs

	Positives	Negatives
Total		
Myocardial Infarction		
Upper GI Bleed		
Acute Liver Injury		
Acute Renal Failure		

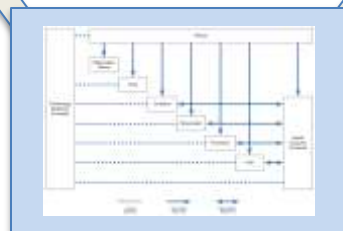
Test cases

+ EU-ADR replication

- Improve HOI definitions
- Explore false positives



- Evaluate study design decisions (EDDIE)



Methods development

- Methods enhancements
- *Multivariate self-controlled case series*
- Increased parameterization
- *Case-control, new user cohort designs*
- Application of existing tools
- *ICTPD, OS, LGPS, DP*

- Expand CDM for additional use cases

Observational data

Real-world performance:



+ OMOP Distributed Partners
+ EU-ADR network

Simulated data:



2011 Test Cases

- Narrowed focus to four Health Outcomes of Interest
 - Acute Myocardial Infarction
 - Gastrointestinal Hemorrhage
 - Acute Renal Failure
 - Acute Liver Injury
- Broader set of test cases for four HOIs
 - 166 positive controls
 - 375 negative controls
- Same experimental process and analysis as initial research
 - Same operating characteristics; specificity, sensitivity at various thresholds, AUC, etc
 - Adding subgroup analysis within the updated test cases

2011 OMOP Funded Collaborations

Organization	Project
Erasmus University Medical Center	Detection of Long Term Adverse Drug Reactions in Electronic HealthCare Data using OSIM 2 and OMOP Laboratory Data with the Longitudinal Evaluation of Observational Profiles of Adverse Events Related to Drugs [LEOPARD] method.
Indiana University	Cohort Design Method enhancements
Uppsala Monitoring Centre	IC Temporal Pattern Discovery Method Improvements and In-Depth Analysis of Clinical Outcomes of Interest
Massachusetts General Hospital	Validating OMOP Results with Reproducible Detailed Data Investigation (Antibiotics & Acute Renal Failure, Typical Antipsychotics & GI Ulcer Hospitalization, and Warfarin & Hip Fracture)
Auburn University	Developing a Structured Process for Measuring and Interpreting Health Outcomes of Interest in the OMOP Common Data Model (starting with Acute Liver Injury)
EU-ADR	<i>In negotiation:</i> Extending OMOP to the EU-ADR Network across six or seven sites within Italy, The Netherlands, and Denmark

How can you get an idea of the range of rational choices for surveillance/epidemiology of a particular association?

Epidemiology Design Decision Inventory and Evaluation (EDDIE)

- An on-line survey that captures:
 - respondent training
 - background
 - experience (general and specific to drugs/HOIs)
- Presents a number of drug-HOI pairs and a series of choices that one would make in studying the association
- Attempts to capture from a broad audience the choices and some of the classification/characterization that we use
- To find out more information, go to the web-based survey - <http://www.surveygizmo.com/s3/555906/EDDIE> OR the OMOP website: <http://omop.fnih.org>

Ongoing Research Priorities

OMOP is pursuing the continuation of its mission to improve our ability for drug safety (and benefit) monitoring:

- **Advance methodological research** to explore the performance of methods over time, within specific populations of interest, and across a broader array of medical products and health outcomes
- **Refine and enhance OMOP's tools and capabilities** to translate research into practice
- **Sustain the shared resource (research lab)** so the research community maintains an open forum for collaborative research
- **Develop approaches to incorporating benefits** including increased application of clinical data to help ascertain benefits
- **Additional research with these methods moves us from 'risk identification' to 'risk refinement'** with same empiricism

OMOP Team

Research Investigators

The lead scientists for the OMOP project who guide and participate in the research across all project phases

William DuMouchel

Chief Statistical Scientist, Oracle Health Sciences

Abraham G. Hartzema, PharmD, MSPH, PhD, FISPE

Professor and Eminent Scholar Pharmaceutical Outcomes & Policy, Perry A. Foote Chair in Health Outcomes Research, University of Florida College of Pharmacy

David Madigan, PhD

Professor of Statistics, Columbia University

J. Marc Overhage, MD, PhD

Chief Medical Informatics Officer, Siemens Health Services

Patrick Ryan, PhD

Associate Director, Analytical Epidemiology, Johnson & Johnson Pharmaceutical Research and Development

Martijn Schuemie, PhD

Assistant Professor, Erasmus University Medical Center of Rotterdam
Visiting Research Scientist, Columbia University

Paul Stang, PhD

Senior Director, Epidemiology, Johnson & Johnson Pharmaceutical Research and Development

Marc Suchard, MD, PhD

Professor, University of California, Los Angeles

Management Team

FNIH provides program management, grants management, and operational support.

Executive Director

Thomas Scarnecchia, MS
VP & CTO, Digital Aurora

Program Managers

Emily Welebob, RN, MS
Christian Reich, MD, PhD

OMOP Contact Information

Thomas Scarnecchia

Executive Director, Observational Medical Outcomes Partnership

tscarnecchia@fnih.org

802 362 8111

OMOP website: <http://omop.fnih.org>

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- Welcome Call to Order (Shelley Price)
- Introduction HIMSS Life Sciences Roundtable -- Scope and Vision (Shelley Price, Stefanie Bednarczyk)
- Topic discussion Advancing the Science of Observational Data Analysis in Life Sciences (J. Marc Overhage, OMOP)
- Wrap-Up** **(Shelley Price)**

Adjournment





Wrap-up



- Web page
 - http://www.himss.org/asp/topics_FocusDynamic.asp?faid=518
- Next meeting
 - 3rd Wednesday of the month, 11am-12pm ET
 - *Thursday, December 21, 2011*
 - *Open to HIMSS members*
 - *HIMSS members contact Nancy Devlin*
 - ndevlin@himss.org



Leadership and Contact Information

Chairperson:

Stefanie Bednarczyk

Life Sciences Account Executive

Health Solutions Business Unit

SAIC

STEFANIE.M.BEDNARCZYK@saic.com

HIMSS Staff Liaison:

Shelley Price

Director, Payer and Life Sciences

HIMSS

sprice@himss.org

Nancy Devlin

Senior Associate, Payer and Life Sciences

HIMSS

ndevlin@himss.org