



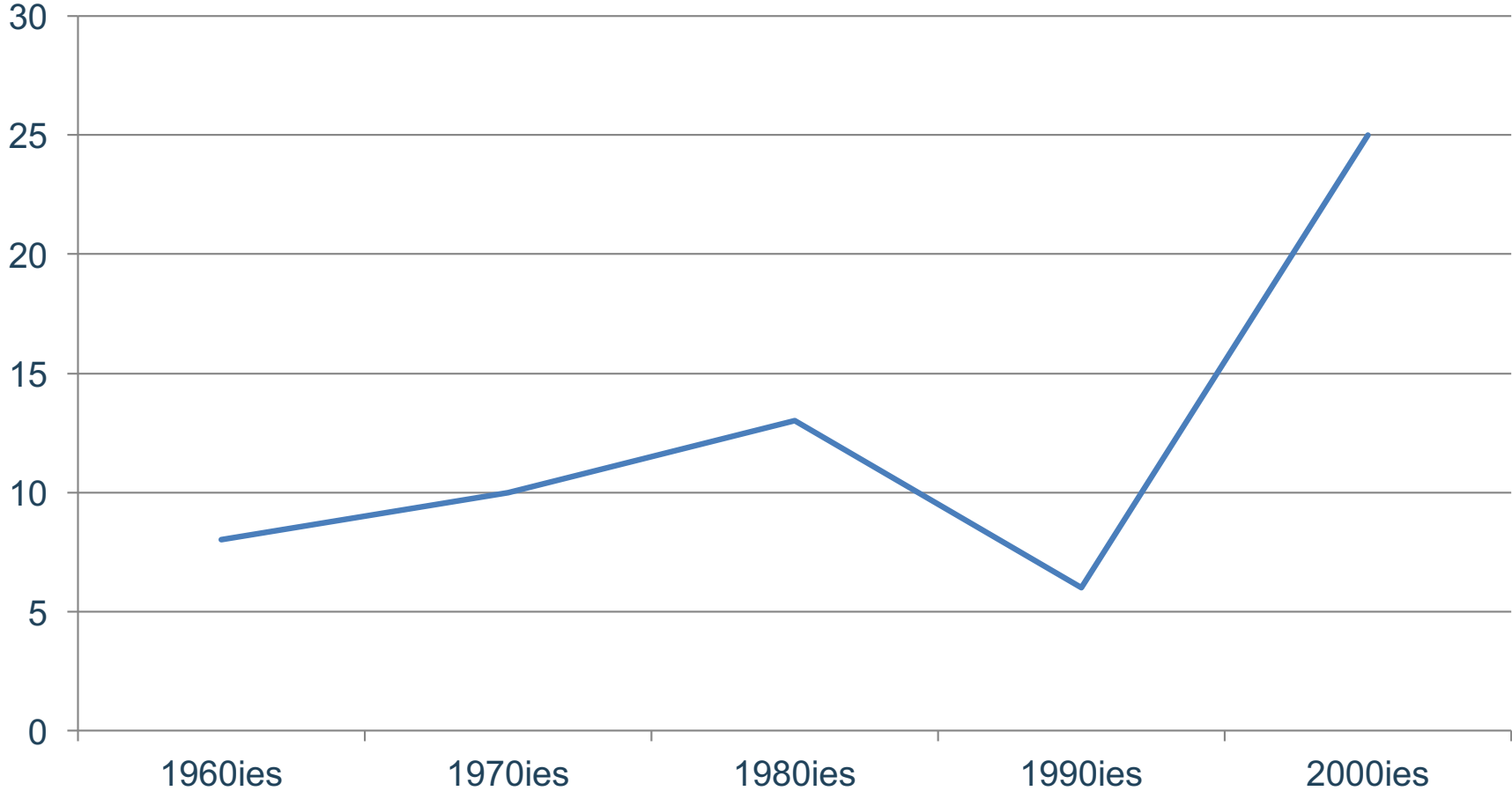
# OHDSI

SNOMED-CT Expo  
19-October-2018



# FDA Regulatory Action over Time

## Number of FDA-caused Withdrawals



# FDAAA calls for establishing Risk Identification and Analysis System

## SEC. 905. ACTIVE POSTMARKET RISK IDENTIFICATION AND ANALYSIS.

(a) IN GENERAL.—Subsection (k) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

“(3) ACTIVE POSTMARKET RISK IDENTIFICATION.—

“(A) DEFINITION.—In this paragraph, the term ‘data’ refers to information with respect to a drug approved under this section or under section 351 of the Public Health Service Act, including claims data, patient survey data, standardized analytic files that allow for the pooling and analysis of data from disparate data environments, and any other data deemed appropriate by the Secretary.

“(B) DEVELOPMENT OF POSTMARKET RISK IDENTIFICATION AND ANALYSIS METHODS.—The Secretary shall, not later than 2 years after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, in collaboration with public, academic, and private entities—

“(i) develop methods to obtain access to disparate data sources including the data sources specified in subparagraph (C);

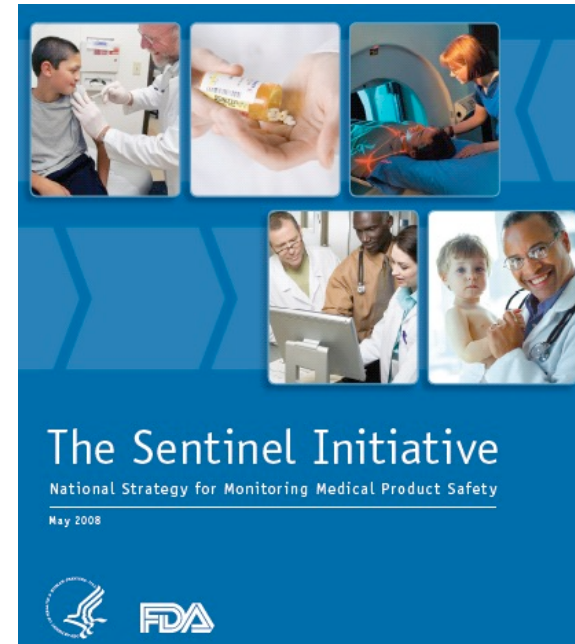
“(ii) develop validated methods for the establishment of a postmarket risk identification and analysis system to link and analyze safety data from multiple sources, with the goals of including, in aggregate—

“(I) at least 25,000,000 patients by July 1, 2010; and

“(II) at least 100,000,000 patients by July 1, 2012; and

“(iii) convene a committee of experts, including individuals who are recognized in the field of protecting data privacy and security, to make recommendations to the Secretary on the development of tools and methods for the ethical and scientific uses for, and communication of, postmarketing data specified under subparagraph (C), including recommendations on the development of effective research methods for the study of drug safety questions.

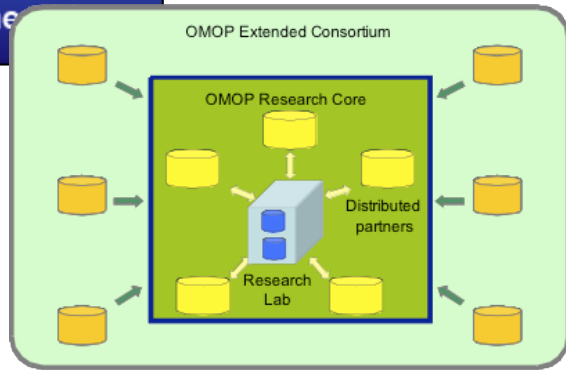
“(C) ESTABLISHMENT OF THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—



## Risk Identification and Analysis System:

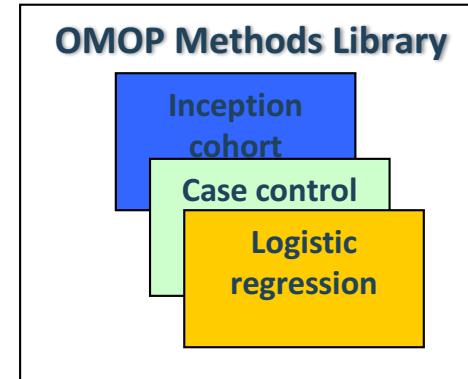
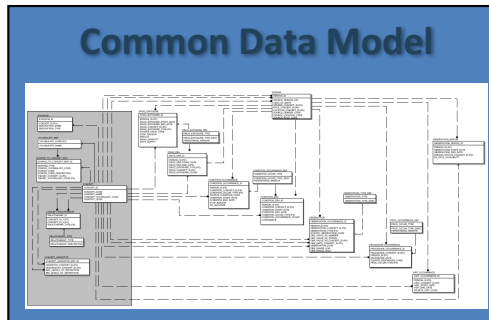
a systematic and reproducible process to efficiently generate evidence to support the characterization of the potential effects of medical products from across a network of disparate observational healthcare data sources

# OMOP Experiment 1 (2009-2010)



- 10 data sources
- Claims and EHRs
- 200M+ lives

- Open-source
- Standards-based



- 14 methods
- Epidemiology designs
- Statistical approaches adapted for longitudinal data



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

# OMOP Experiment 2 (2011-2012)

## Observational Data

4 claims databases

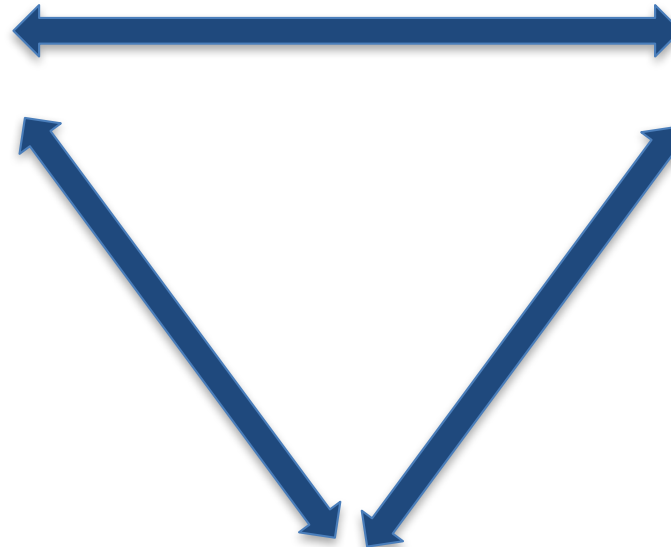


1 ambulatory EMR



## Methods

- Case-Control
- New User Cohort
- Disproportionality methods
- ICTPD
- LGPS
- Self-Controlled Cohort
- SCCS



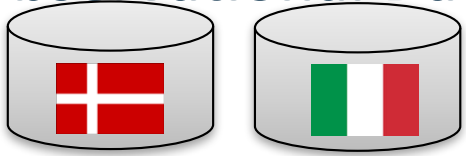
## Drug-outcome pairs

	Positives	Negatives
<b>Total</b>	165	234
Myocardial Infarction	36	66
Upper GI Bleed	24	67
Acute Liver Injury	81	37
Acute Renal Failure	24	64

# European OMOP Experiment

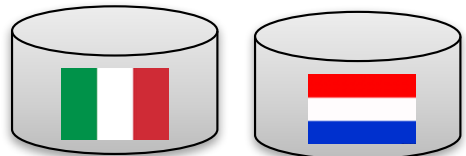


## Observational Data



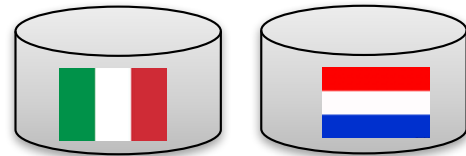
ARS

IPCI



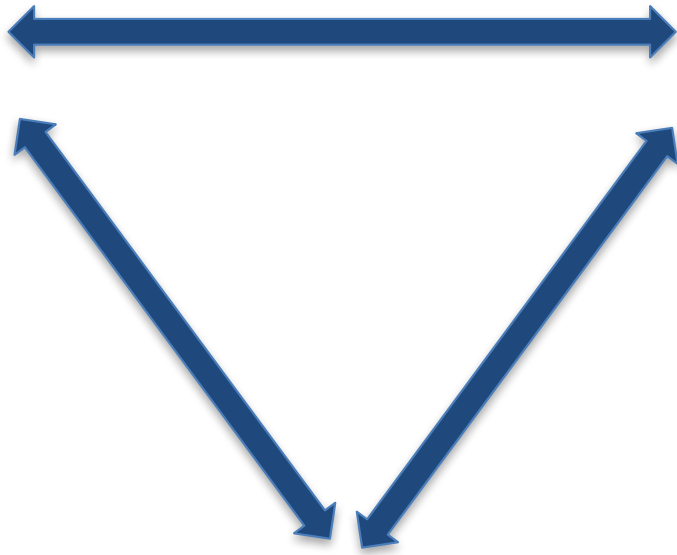
HS

PHARMO



## Methods

- Case-Control
- New User Cohort
- Disproportionality methods
- ICTPD
- LGPS
- Self-Controlled Cohort
- SCCS



## Drug-outcome pairs

	Positives	Negatives
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# Ground Truth for OMOP Experiment

	Positive controls	Negative controls	Total
<b>Acute Liver Injury</b>	81	37	118
<b>Acute Myocardial Infarction</b>	36	66	102
<b>Acute Renal Failure</b>	24	64	88
<b>Upper Gastrointestinal Bleeding</b>	24	67	91
<b>Total</b>	165	234	399

isoniazid

fluticasone

indomethacin

clindamycin

ibuprofen

loratadine

sertraline

pioglitazone

Criteria for positive controls:

- Event listed in Boxed Warning or Warnings/Precautions section of active FDA structured product label
- Drug listed as 'causative agent' in Tisdale et al, 2010: Drug-Induced Diseases
- Literature review identified no powered studies with refuting evidence of effect

Criteria for negative controls:

- Event not listed anywhere in any section of active FDA structured product label
- Drug not listed as 'causative agent' in Tisdale et al, 2010: Drug-Induced Diseases
- Literature review identified no powered studies with evidence of potential positive association

Observational  
Medical  
Outcomes  
Partnership

Results





# Main findings in OMOP experiment

- Heterogeneity in estimates due to choice of database
- Heterogeneity in estimates due to analysis choices
- Except little heterogeneity due to outcome definitions
- Good performance (AUC > 0.7) in distinguishing positive from negative controls for optimal methods when stratifying by outcome and restricting to powered test cases
- Self controlled methods perform best for all outcomes

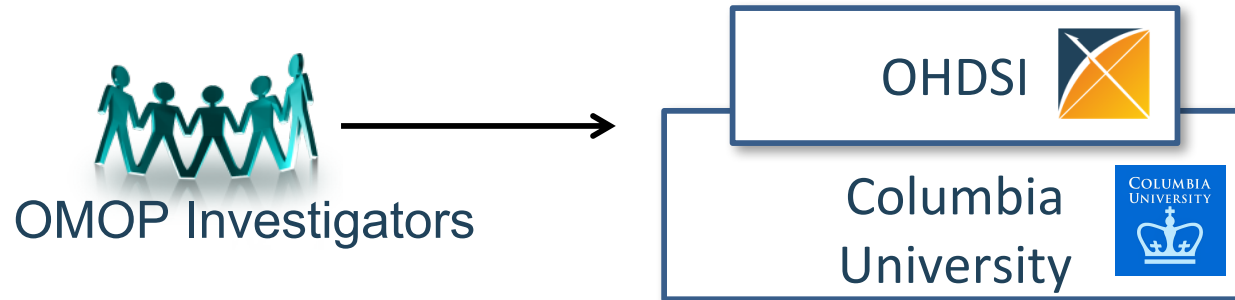


# Observational Health Data Sciences and Informatics (OHDSI) Plans and Ambitions





# Fate of OMOP - OHDSI



- The Observational Health Data Sciences and Informatics (OHDSI) program is a **multi-stakeholder, interdisciplinary collaborative** to create **open-source** solutions that bring out the value of observational health data through large-scale analytics
- OHDSI has established an **international network of researchers and observational health databases** with a central coordinating center housed at Columbia University
  - Public, Open
  - Not Pharma-funded
  - International

<http://ohdsi.org>



# OHDSI's Mission & Vision

To improve health by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care.

A world in which observational research produces a comprehensive understanding of health and disease.

Join us on the journey

<http://ohdsi.org>



# OHDSI: a global community



## OHDSI Collaborators:

- >220 researchers in academia, industry and government
- >21 countries

## OHDSI Data Network:

- >114 databases from 19 countries
- 1.9 billion patients records (duplicates)
- ~222 million non-US patients

# Observational Research has a Problem



**OHDSI**

OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS





BMJ 2010; 341:c4444

BMJ

**RESEARCH**

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## Oral bisphosphonates and risk of cancer of oesophagus, stomach, and colorectum: case-control analysis within a UK primary care cohort

Jane Green, clinical epidemiologist,<sup>1</sup> Gabriela Czanner, statistician,<sup>1</sup> Gillian Reeves, statistical epidemiologist,<sup>1</sup> Joanna Watson, epidemiologist,<sup>1</sup> Lesley Wise, manager, Pharmacoepidemiology Research and Intelligence Unit,<sup>2</sup> Valerie Beral, professor of cancer epidemiology<sup>1</sup>



JAMA®

# Exposure to Oral Bisphosphonates and Risk of Esophageal Cancer

Chris R. Cardwell, PhD

Christian C. Abnet, PhD

Marie M. Cantwell, PhD

Liam J. Murray, MD

**Context** Use of oral bisphosphonates has increased dramatically in the United States and elsewhere. Esophagitis is a known adverse effect of bisphosphonate use, and recent reports suggest a link between bisphosphonate use and esophageal cancer, but this has not been robustly investigated.

**Objective** To investigate the association between bisphosphonate use and esoph-





# What is the quality of the current evidence from observational analyses?

ORIGINAL CONTRIBUTION

# JAMA

## Exposure to Oral Bisphosphonates and Risk of Esophageal Cancer

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**Objective** To investigate the association between bisphosphonate use and risk of esophageal and gastric cancer.

August 2010: "Among patients in the UK General Practice Research Database, the use of oral bisphosphonates was not significantly associated with incident esophageal or gastric cancer"

...cause serious esophagitis in some users.<sup>4,5</sup> Crystalline material that resembles ground alendronate tablets has been found on biopsy in patients with bisphosphonate-related esophagitis, and follow-up endoscopies have shown that abnormalities remain after the esophagitis heals.<sup>6</sup> Reflux esophagitis is an established risk factor for esophageal cancer through the Barrett pathway.<sup>7,9</sup> It is not known whether bisphosphonate-related esophagitis can also increase esophageal cancer risk. However, the US Food and Drug Administration recently reported 23 cases of esophageal cancer (between 1995 and 2008) in patients using the bisphosphonate alen-

...there were 41 826 members in each cohort (81% were aged 40 years or over, mean age 61.4 years). One hundred sixteen esophageal or gastric cancers occurred in the bisphosphonate cohort and 115 (72%) in the control cohort. The incidence of esophageal and gastric cancer was 0.44 per 1000 person-years of risk in both the bisphosphonate and control cohorts. The incidence of esophageal cancer alone in the bisphosphonate cohort was 0.44 and 0.44 per 1000 person-years of risk, respectively. The incidence of esophageal and gastric cancer combined between bisphosphonate use (adjusted hazard ratio, 0.96 [95% confidence interval, 0.77-1.49]). There also was no difference in risk of esophageal cancer by duration of bisphosphonate intake.

**Conclusion** Among patients in the UK General Practice Research Database, the use of oral bisphosphonates was not significantly associated with incident esophageal or gastric cancer.

JAMA. 2010;304(6):657-663

Large studies with appropriate comparison groups, adequate follow-up, and appropriate outcomes will determine whether the risk of esophageal cancer increases with

# BMJ

## RESEARCH

## Oral bisphosphonates and risk of cancer of oesophagus, stomach, and colorectum: case-control analysis within a UK primary care cohort

Jane Green, clinical epidemiologist,<sup>1</sup> Gabriela Czanner, statistician,<sup>1</sup> Gillian Reeves, statistical epidemiologist,<sup>1</sup> Joanna Watson, epidemiologist,<sup>1</sup> Lesley Wise, manager, Pharmacoepidemiology Research and Intelligence Unit,<sup>2</sup> Valerie Beral, professor of cancer epidemiology<sup>1</sup>

<sup>1</sup>Epidemiology Unit, of Oxford, Oxford  
<sup>2</sup>Medicines and Healthcare Regulatory Agency, Research on Safety and Quality, London, UK  
Correspondence to: J Green  
@ceus.ox.ac.uk  
BMJ 2010;341:e4444  
bmj.e4444

### ABSTRACT

**Objective** To examine the hypothesis that risk of esophageal, but not of gastric or colorectal, cancer is increased in users of oral bisphosphonates.  
**Design** Nested case-control analysis within a primary care cohort of about 6 million people in the UK, with prospectively recorded information on prescribing of bisphosphonates.

**Setting** UK General Practice Research Database cohort.  
**Participants** Men and women aged 40 years or over—2954 with esophageal cancer, 2018 with gastric cancer, and 10 641 with colorectal cancer, diagnosed in 1995–2005. Exposed cases were matched for age, sex, region, and primary and secondary care, referrals to outpatient

**Conclusions** The risk of oesophageal cancer increased with 10 or more prescriptions for oral bisphosphonates and with prescriptions over about a five year period. In Europe and North America, the incidence of oesophageal cancer at age 60–79 is typically 1 per 1000 population over five years, and this is estimated to increase to about 2 per 1000 with five years' use of oral bisphosphonates.

### INTRODUCTION

Adverse gastrointestinal effects are common among people who take oral bisphosphonates for the prevention and treatment of osteoporosis; they range from dyspepsia, nausea, and abdominal pain to erosive

Sept 2010: "In this large nested case-control study within a UK cohort [General Practice Research Database], we found a significantly increased risk of oesophageal cancer in people with previous prescriptions for oral bisphosphonates"

not vary by age, sex, smoking, alcohol intake, or body mass index. The risk of esophageal cancer was significantly increased in people with previous prescriptions for oral bisphosphonates, but not in people with previous prescriptions for intravenous bisphosphonates. The risk of gastric cancer was not significantly increased in people with previous prescriptions for oral bisphosphonates, but was significantly increased in people with previous prescriptions for intravenous bisphosphonates. The risk of colorectal cancer was not significantly increased in people with previous prescriptions for oral bisphosphonates, but was significantly increased in people with previous prescriptions for intravenous bisphosphonates.



# What is the quality of the current evidence from observational analyses?

ORIGINAL CONTRIBUTION

**JAMA**

## Oral Fluoroquinolones and Risk of Retinal Detachment

Mahyar Etminan, PharmD, MSc (epi)  
Farzin Forooghian, MD, MSc, FRCSC  
James M. Brophy, MD, PhD, FRCPC  
Steven T. Bird, PharmD  
David Maberley, MD, MSc, FRCSC

**Context** Fluoroquinolones have been associated with numerous case reports of ocular safety, particularly retinal detachment. **Objective** To examine the risk of developing a retinal detachment in patients taking oral fluoroquinolones. **Design, Setting, and Population** Retrospective cohort study in British Columbia, Canada.

**Importance** A recent study of ophthalmologic patients found a strong association between fluoroquinolone use and retinal detachment. Given the prevalent use of fluoroquinolones, this could, if confirmed in the general population, translate to many excess cases of retinal detachment that are potentially preventable.

**Main Outcome Measures** The adjusted rate ratio (ARR) for incident retinal detachment was 1.29 (95% CI, 0.53 to 3.13) for current use (day 1 to day 30) compared with nonuse.

**Results** A total of 566 cases of retinal detachment occurred, of which 465 (82%) were rhegmatogenous detachments; 72 in fluoroquinolone users and 494 in control nonusers. The crude incidence rate was 25.3 cases per 100 000 person-years in current users, 18.9 in recent users, 26.8 in past users, and 24.8 in distant users compared with 19.0 in nonusers. Compared with nonuse, fluoroquinolone use was not associated with a significantly increased risk of retinal detachment: the adjusted RRs were 1.29 (95% CI, 0.53 to 3.13) for current use;

Research

**JAMA**

## Association Between Oral Fluoroquinolone Use and Retinal Detachment

Björn Pasternak, MD, PhD; Henrik Svanström, MSc; Mads Melbye, MD, DrMedSci; Anders Hviid, MSc, DrMedSci

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← Editorial page 2151

← JAMA Patient Page 2212

+ Supplemental content at jama.com

April 2012: “Patients taking oral fluoroquinolones were at a higher risk of developing a retinal detachment”

Dec 2013: “Oral fluoroquinolone use was not associated with increased risk of retinal detachment”



# What is the quality of the current evidence from observational analyses?

BJCP British Journal of Clinical Pharmacology

DOI:10.1111/j.1365-2125.2012.04325.x

## Pioglitazone and bladder cancer: a propensity score matched cohort study

Li Wei, Thomas M. MacDonald

Medicines Monitoring Unit (MEMO), Division of Clinical Pharmacology, Medical School, Dundee, UK

# BMJ

BMJ 2012;344:e3645 doi: 10.1136/bmj.e3645 (Published 31 May 2012)

Page 1 of 11

BJCP May 2012: "In this study population, pioglitazone does not appear to be significantly associated with an increased risk of bladder cancer in patients with type 2 diabetes."

## RESEARCH

### WHAT IS ALREADY KNOWN ABOUT THIS SUBJECT

- Pioglitazone is mainly used in combination with diet and exercise and other anti-diabetic medications to treat type 2 diabetes mellitus.
- Long term use of pioglitazone (as part of therapy) may be associated with an increased risk of bladder cancer.

## The use of pioglitazone and the risk of bladder cancer: a propensity score matched case-control study

BMJ May 2012: "The use of pioglitazone is associated with an increased risk of incident bladder cancer among people with type 2 diabetes."

### WHAT THIS STUDY ADDS

- In this study population, pioglitazone does not appear to be significantly associated with an increased risk of bladder cancer in patients with type 2 diabetes.

Jonathan Assayag *graduate student*, Agnieszka Majdan *endocrinologist*<sup>4</sup>, Michael N Pollak *oncologist and professor*<sup>2</sup>, Samy Suissa *professor*<sup>5</sup>

Christian B Filion *assistant professor*<sup>1,3</sup>,

<sup>1</sup>Centre for Clinical Epidemiology, Lady Davis Institute, Jewish General Hospital, 3755 Côte Sainte-Catherine, H-425.1, Montreal, Quebec, Canada, H3T 1E2; <sup>2</sup>Department of Oncology, McGill University, Montreal, Quebec, Canada; <sup>3</sup>Division of Clinical Epidemiology, McGill University, Montreal; <sup>4</sup>Division of Endocrinology, Jewish General Hospital, Montreal; <sup>5</sup>Department of Epidemiology, Biostatistics, and Occupational Health, McGill University, Montreal



# What is the quality of the current evidence from observational analyses?

PERSPECTIVE  The NEW ENGLAND JOURNAL of MEDICINE  
DABIGATRAN AND POSTMARKETING

## Dabigatran and Postmarketing Reports of Bleeding

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

Nov2012: FDA released risk communication about the bleeding risk of dabigatran, based on unadjusted cohort analysis performed within Mini-Sentinel

ports of bleeding were anticipated hemorrhagic strokes than warfarin and degree

but the rate of was unusually higher than the reported bleeding with warfarin, which is a coagulant of choice for many years before dabigatran was approved. In contrast, a trial that supported dabigatran (Randomized Evaluation of Long-Term Therapy [RE-LY]) comparing warfarin with dabigatran in patients with non-valvular atrial fibrillation,<sup>1</sup> showed that dabigatran conferred less bleeding.

The postmarketing bleeding with dabigatran has been discussed in the media as well as in discussions in the medical community about the safety of the drug. Many authors cited the postmarketing reports of bleeding

### CLINICIAN UPDATE

## Circulation

JOURNAL OF THE AMERICAN HEART ASSOCIATION

### The Promise of Pharmacoepidemiology in Helping Clinicians Assess Drug Risk

Jerry Avorn, MD

Aug2013: "However, the absence of any adjustment for possible confounding and the paucity of actual data made the analysis unsuitable for informing the care of patients"

### Letters

## JAMA Internal Medicine

Formerly Archives of Internal Medicine

### RESEARCH LETTER

### A Comparison of Results of the US Food and Drug Administration's Mini-Sentinel Program With Randomized Clinical Trials: The Case of Gastrointestinal Tract Bleeding With Dabigatran

The US Food and Drug Administration (FDA) recently started

Results | Twenty-seven articles were identified using the MEDLINE search. Three articles provided data on incident GI tract bleeding with dabigatran vs warfarin.<sup>2-4</sup> A search of the FDA website provided additional data on GI tract bleeding for one of these clinical trials<sup>5</sup> and search of the clinical trials registry of manufacturer provided data for another clinical trial.<sup>6</sup>

Dec2013: "This analysis shows that the RCTs and Mini-Sentinel Program show completely opposite results"

tract bleeding risk of dabigatran vs warfarin with the results of randomized clinical trials (RCTs).

Methods | To obtain the results of RCTs regarding GI tract bleeding, a literature search was performed using MEDLINE through July 2013 with the search term "dabigatran AND warfarin" limited to RCTs. This search was supplemented with examination of the FDA website for additional data, as well as a search of the clinical trial registry website maintained by dabigatran's manufacturer. The RCTs

directly comparing dabigatran to warfarin that reported incident GI tract bleeding were then included in a meta-analysis. The meta-analytic risk ratio (RR) of dabigatran vs warfarin for GI tract bleeding was calculated using a fixed-effect model. The results of this meta-analysis were then compared with the results of the Mini-Sentinel Program and

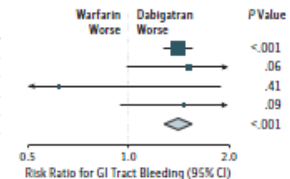
the agency concluded that GI tract bleeding rates are not higher (and indeed lower) with dabigatran, attributed the postmarketing reports of bleeding to "stimulated reporting" and released a reassuring statement about the bleeding risks of this drug.

Discussion | This analysis shows that the RCTs and Mini-Sentinel Program show completely opposite results regarding the GI tract bleeding risk of dabigatran compared with warfarin. The meta-analytic results of the RCTs have very narrow confidence intervals and no heterogeneity, demonstrating the increased risk of GI tract bleeding with dabigatran (vs warfarin) unequivocally. However, the Mini-Sentinel Program reports a greater than 50% decrease in incident GI tract bleeding with dabigatran compared with warfarin.

Observational studies like the Mini-Sentinel Program are inherently problematic owing to several sources of biases. Because of their limitations, the approval process of drugs relies solely on RCTs. Nevertheless, observational studies are still per-

Table 1. Randomized Reporting Gastrointestinal (GI) Tract Bleeding With Dabigatran vs Warfarin (Fixed-Effect Model)

	Total		Risk Ratio (95% CI)	P Value
	Dabigatran	Warfarin		
	12091	6022	1.41 (1.27-1.56)	<.001
	1274	1265	1.50 (0.99-2.29)	.06
	1430	1426	0.62 (0.20-1.90)	.41
	1279	1289	1.47 (0.95-2.27)	.09
	16074	10002	1.41 (1.28-1.55)	<.001





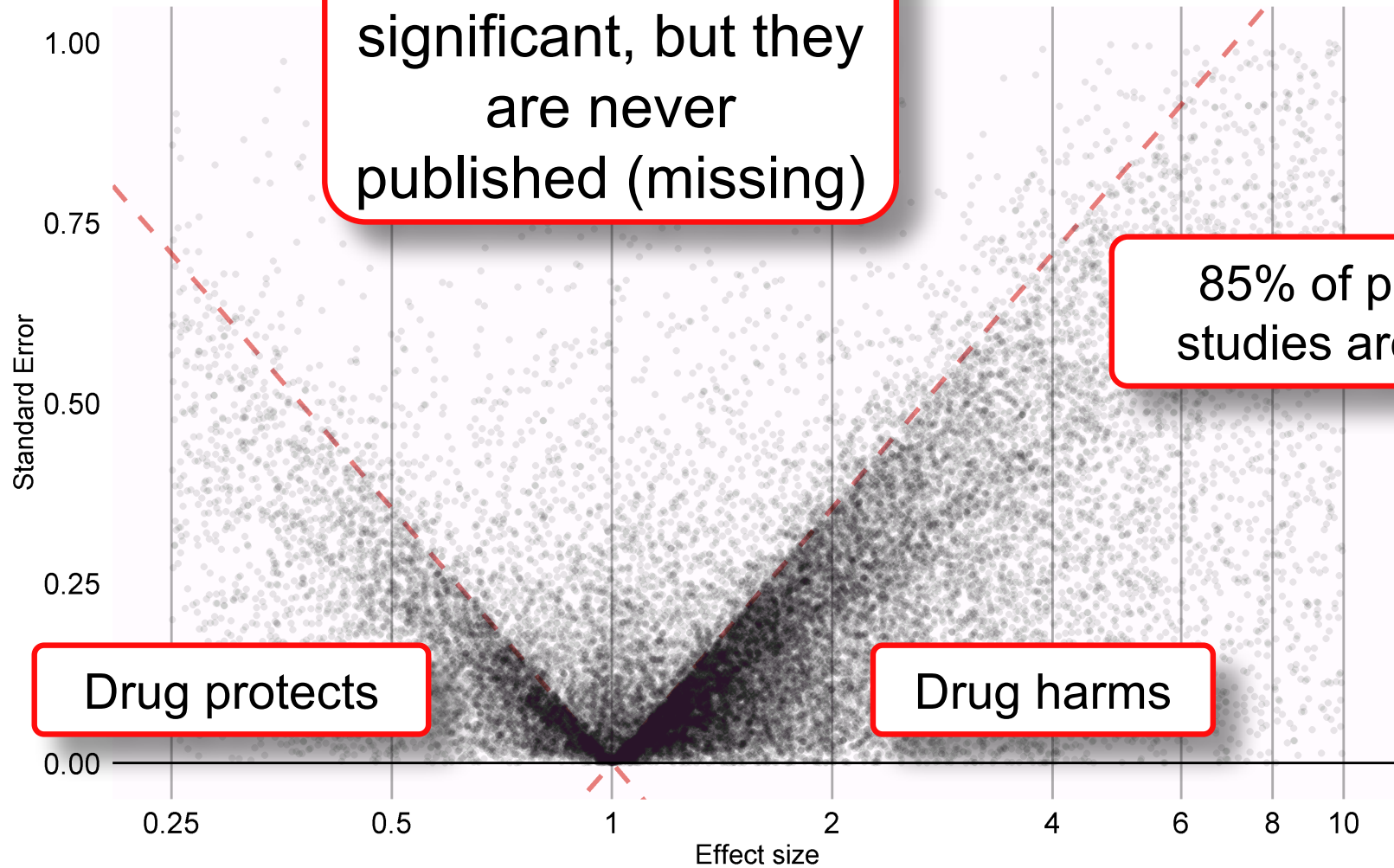
# The current literature is severely biased

In reality, most results are not significant, but they are never published (missing)

85% of published studies are positive

Drug protects

Drug harms



29,982  
estimates  
11,758 papers



# Current pace of evidence generation in healthcare

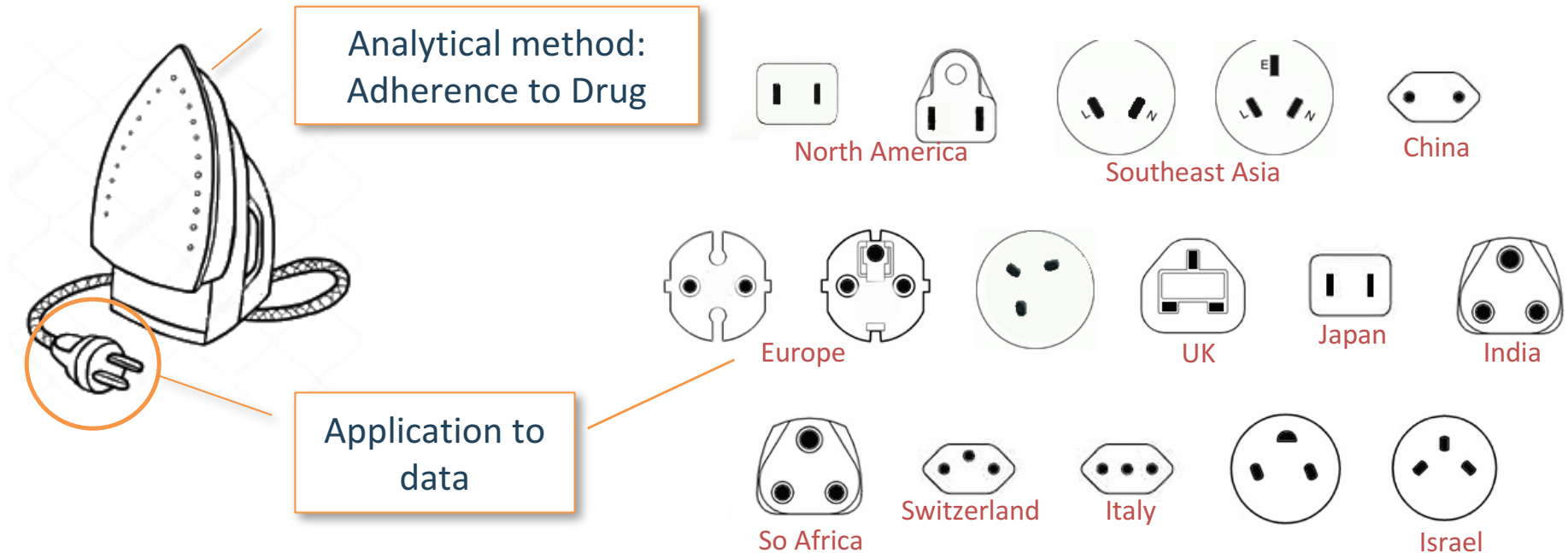
## All health outcomes of interest

All drugs

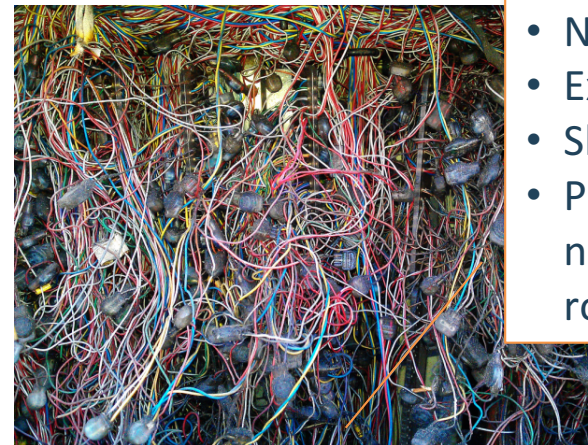
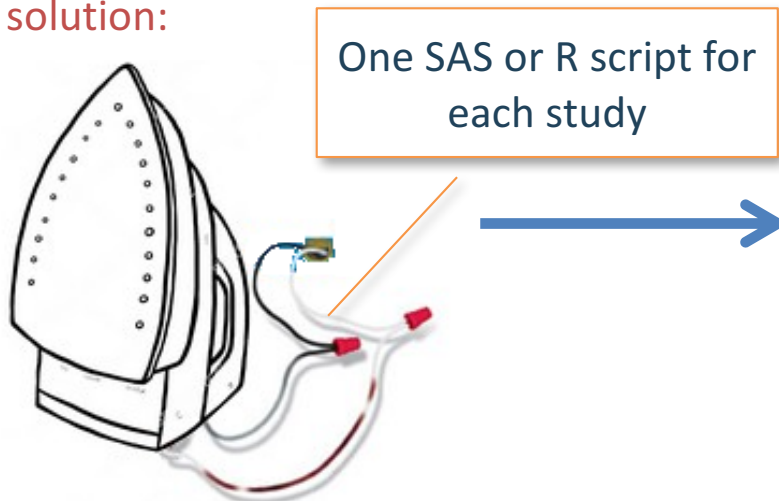


# Current Approach: "One Study – One Script"

"What's the adherence to my drug in the data assets I own?"



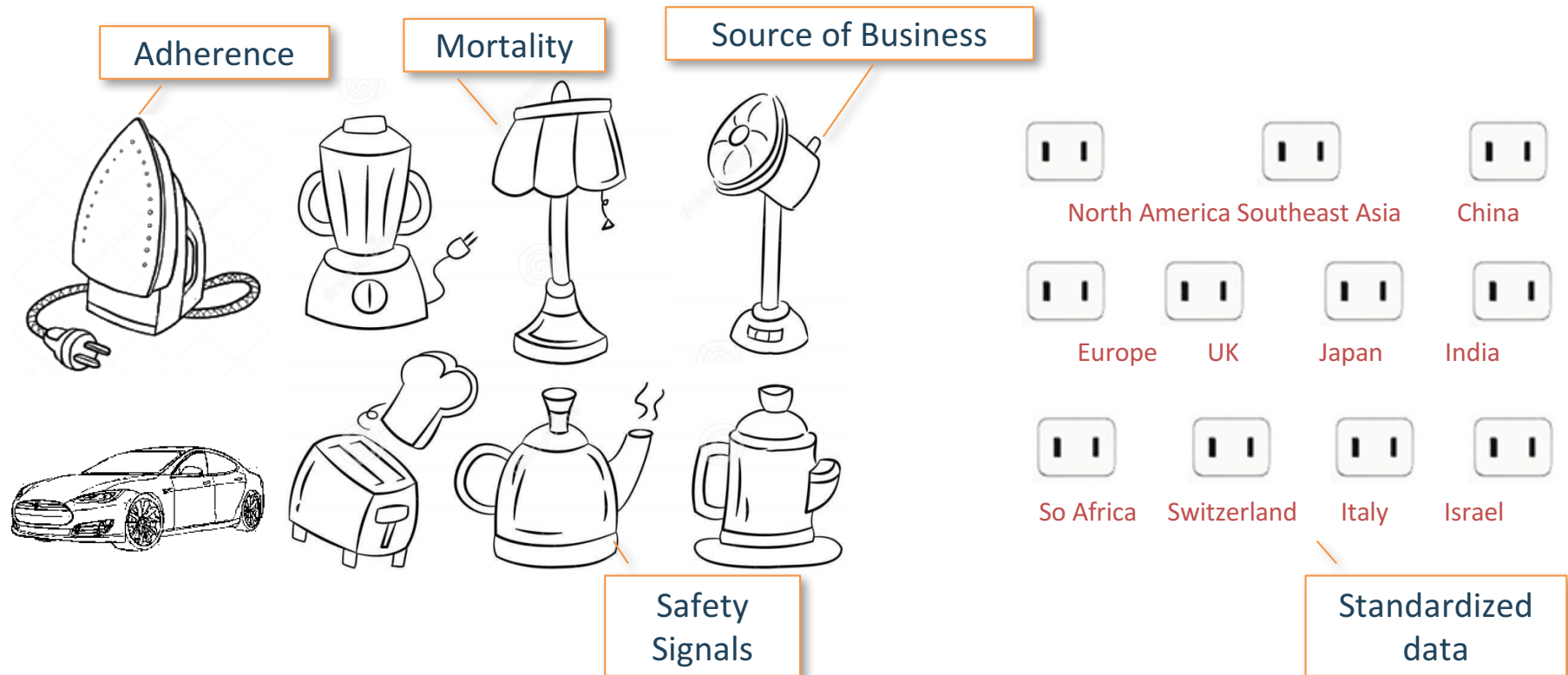
Current solution:



- Not scalable
- Not transparent
- Expensive
- Slow
- Prohibitive to non-expert routine use



# Solution: Data Standardization Enables Systematic Research



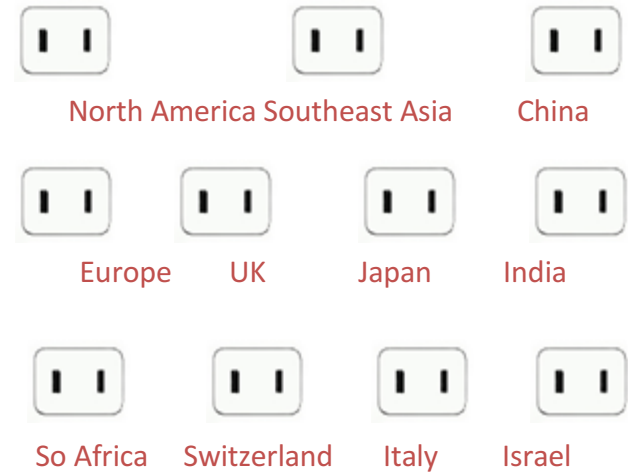
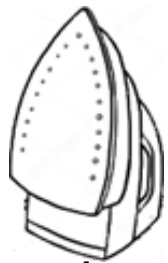
OHDSI Tools

OMOP CDM





# Analytics can be remote





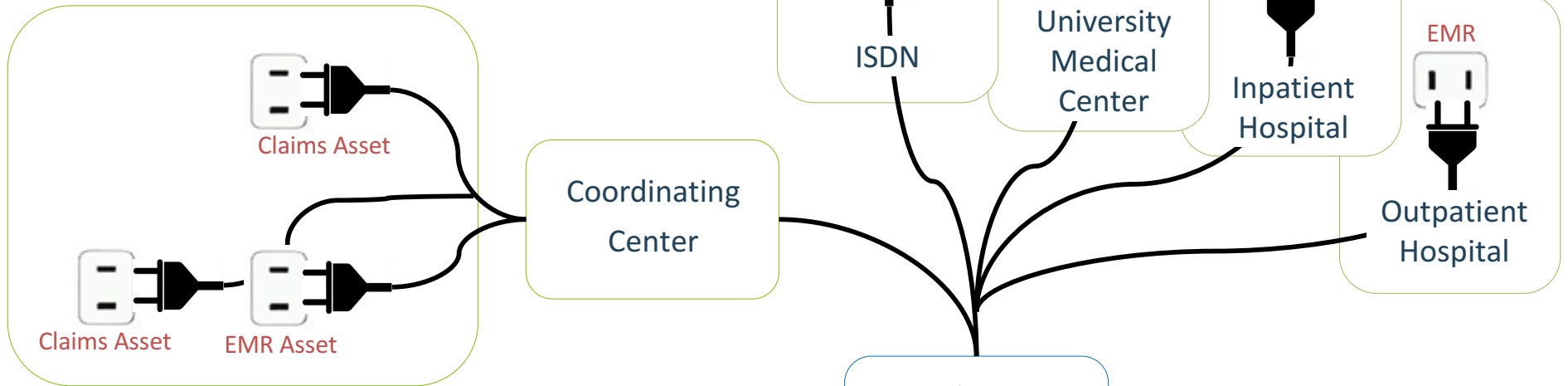
# Analytics can be behind firewall





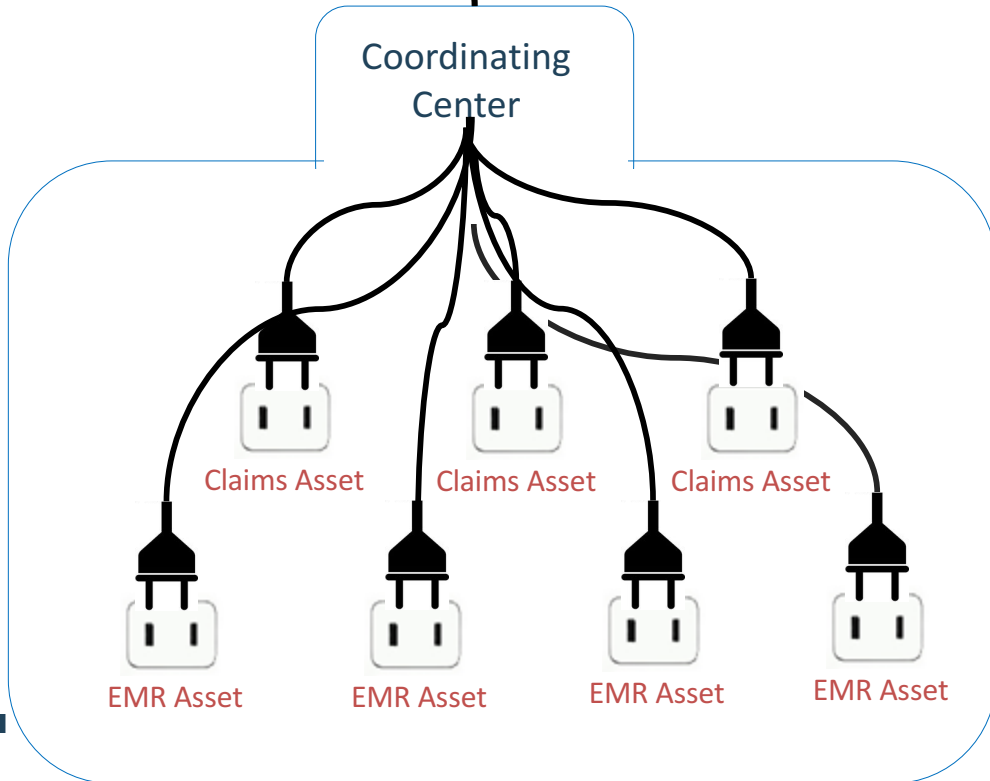
# Network Studies

## Networks of networks



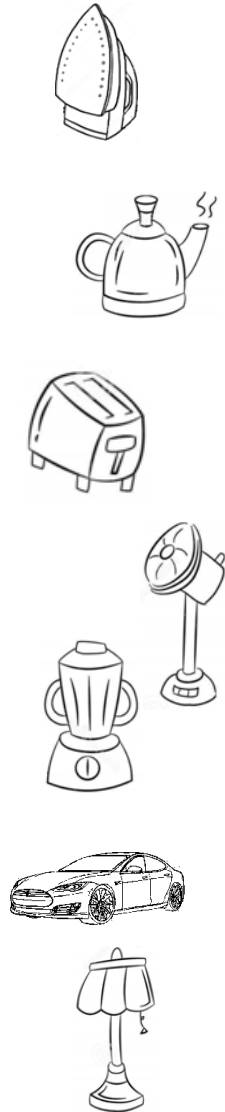
### Another Network

### Network





# A) Incentives for the Node

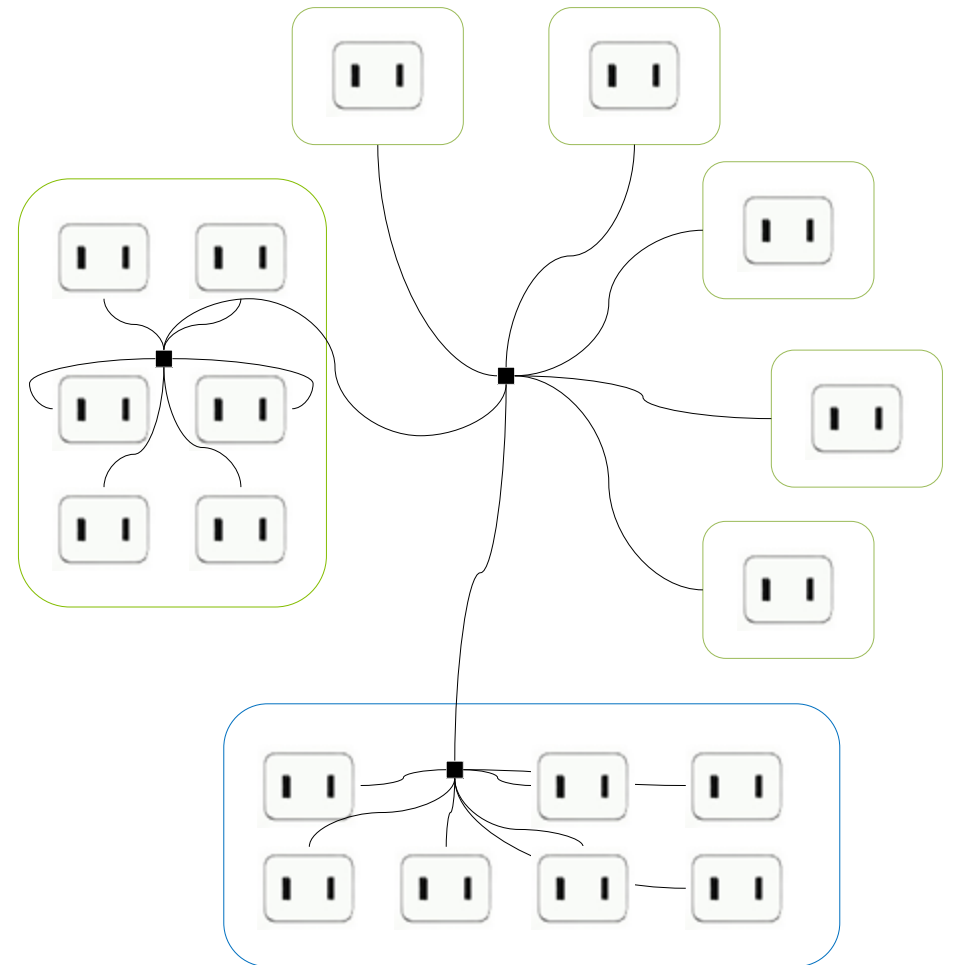


- Enabling data for research
- ~Free Tools, Methods
  - Vocabulary browsing
  - Population characterization
  - Adjudication and validation
  - Population-based estimation
  - Patient-level prediction
- Quality benchmarks
- Scientific reputation
- Potentially money



## b) Feeding the Network

- Foundational
  - CDM
  - Vocabulary, Mapping
  - Community
  - Training
- Trust
  - Open Source
  - Nodes keep control over data
- Methodology
- Technology, tools, automation
- Use cases, scientific impact
- Reciprocity, no autocracy





# Tutorials

- OMOP CDM and Vocabulary
- Overview of the OHDSI Analysis
- OHDSI Tech Stack
- Data ETL
- Cohort Definition/Phenotyping
- Patient-Level Prediction
- Population-level Effect Estimation
- Data Quality

## 2017 Tutorials – OMOP Common Data Model and Standardized Vocabularies

### Faculty:

George Hripcsak, Christian Reich, Erica Voss, Karthik Natarajan, Mark Velez, Mui Van Zandt, Rimma Belenkaya, Don O'Hara, Michael Goodman, Gowtham Rao, Dmytry Dymshyts, Don Torok, Clair Blacketer

### Target Audience:

Data holders who want to apply OHDSI's data standards to their own observational datasets and researchers who want to be aware of OHDSI's data standards so they can leverage data in OMOP CDM format for their own research purposes.

### Videos

2017 OHDSI CDM & Vocabulary Tutorial (1 of 5)

### OHDSI: a global community

**OHDSI Collaborators:**


- >200 researchers in academia, industry and government
- >17 countries




**OHDSI Data Network:**

- >82 databases from 17 countries
- 1.2 billion patients records (as of 2016)
- ~115 million non-US patient records



# Forum, Workgroups



all categories ▾
all tags ▾
Categories
Latest

+ New Topic

Category	Latest	Topics
<p><b>General</b> 50 unread 2 new</p> <p>For general discussion about the OHDSI community and how to get involved.</p>	<p>📌 Welcome to OHDSI! - Please introduce yourself 47 8h</p> <p>Where can I find OHDSI policies on human subjects issues? •new 12h</p> <p>OHDSI Community Call 19Jun2018 1d</p>	<p>1 / day</p> <p>4 / week</p>
<p><b>Implementers</b> 46 unread 1 new</p> <p>For discussion about how to implement the CDM and OHDSI analytics framework in your local environment.</p>	<p>Cerner ETL Workgroup •new 4h</p> <p>Tracking Source References when loading Data from Separated by Systems 2d</p> <p>Epic User Web , Epic ETL documentation/scripts 2 19d</p>	<p>1 / week</p> <p>5 / month</p>
<p><b>Developers</b> 50 unread</p> <p>This forum is for discussion around open-source development of OHDSI applications and other tools that leverage the OMOP CDM.</p>	<p>📌 Open Source Architecture Meeting Notes Jan '15</p> <p>1K sample of simulated CMS SynPUF data in CDMV5 format available for download 6 2d</p> <p>How to push Impala dll v5.3 fixed code 2d</p>	<p>8 / month</p> <p>71 / year</p>
<p><b>Researchers</b> 45 unread 2 new</p> <p>For discussion around CDM-based research, including evidence generation, collaborative research, statistical methods, and other topics of interest to the Research Network.</p>	<p>Potential for Cancer/Oncology Studies in OHDSI—Need your thoughts! 4 11h</p> <p>Building a validated OHDSI outcome library 1 12h</p> <p>Treatment Pathways: Combination drugs (Posting 1) 7 22h</p>	<p>1 / day</p> <p>3 / week</p>
<p><b>CDM Builders</b> 82 unread</p> <p>For discussion of ongoing CDM development, including requirements, vocabulary, and technical aspects.</p>	<p>Multiple race solution? 1d</p> <p>Geographical/Year-Based Multiplier 2d</p> <p>Care sites and specialty, specialty code clean-up 3d</p>	<p>1 / week</p> <p>10 / month</p>
<p><b>Vocabulary Users</b> 63 unread 1 new</p> <p>This forum is for discussion around vocabulary content.</p>	<p>The concepts in CONCEPT table is defined by OHDSI itself? 3h</p> <p>CPT4 Place of Service Codes 5h</p> <p>Sunscreen - Device or Drug •new 7h</p>	<p>2 / day</p> <p>2 / week</p>
<p><b>Collaborators</b></p> <p>For discussion limited to formal OHDSI collaborators.</p>	<p>Sharing Research Results - Authentication Details Feb '15</p>	
<p><b>Leadership</b> 29 unread</p> <p>For discussion amongst the OHDSI Leadership committee.</p>	<p>Tomorrow's leadership call 15June2018 at 11:30am ET 7d</p> <p>Tomorrow's leadership call 8June2018 at 11:30am ET 14d</p> <p>Tomorrow's leadership call - 1June2018 at 11:30am ET 19d</p>	<p>1 / week</p> <p>5 / month</p>




# Atlas, Achilles, Athena

### ATLAS

- Home
- Data Sources
- Vocabulary
- Concept Sets
- Cohort Definitions
- Incidence Rates
- Profiles
- Estimation
- Prediction
- Jobs
- Configuration
- Feedback

Apache 2.0  
open source software


provided by  
  
join the journey

### Dashboard

#### Dashboard Report ( FR2017Q2)

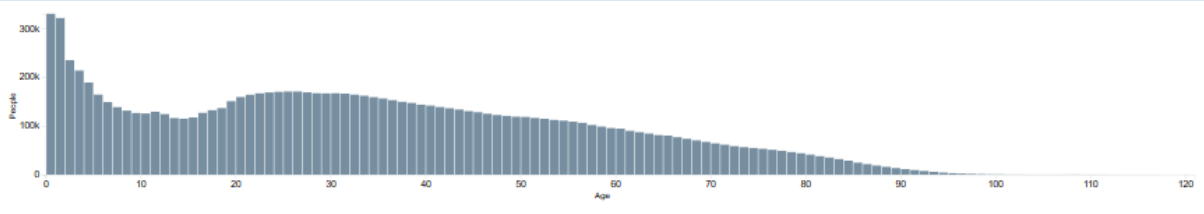
CDM Summary	
Source name	DEFAULT
Number of persons	10.552M

#### Population by Gender

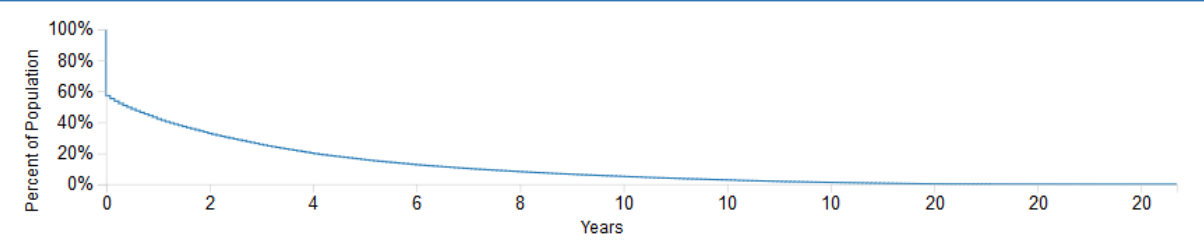


Legend: FEMALE, MALE

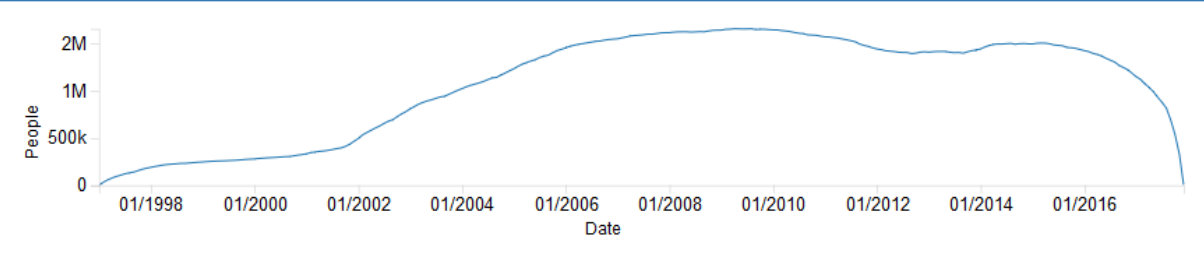
#### Age at First Observation



#### Cumulative Observation



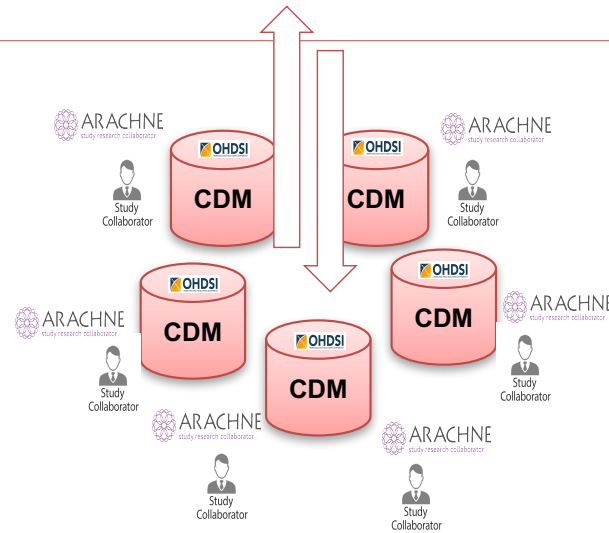
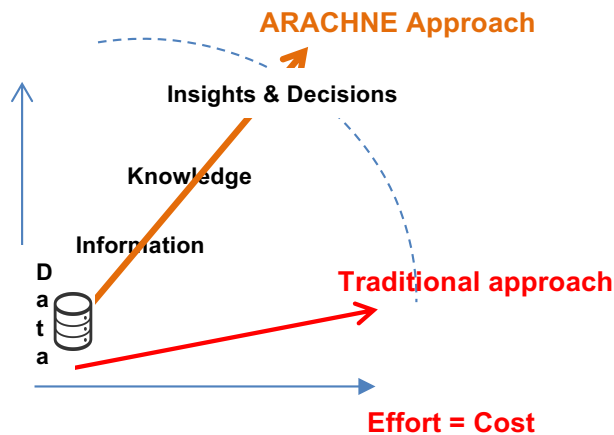
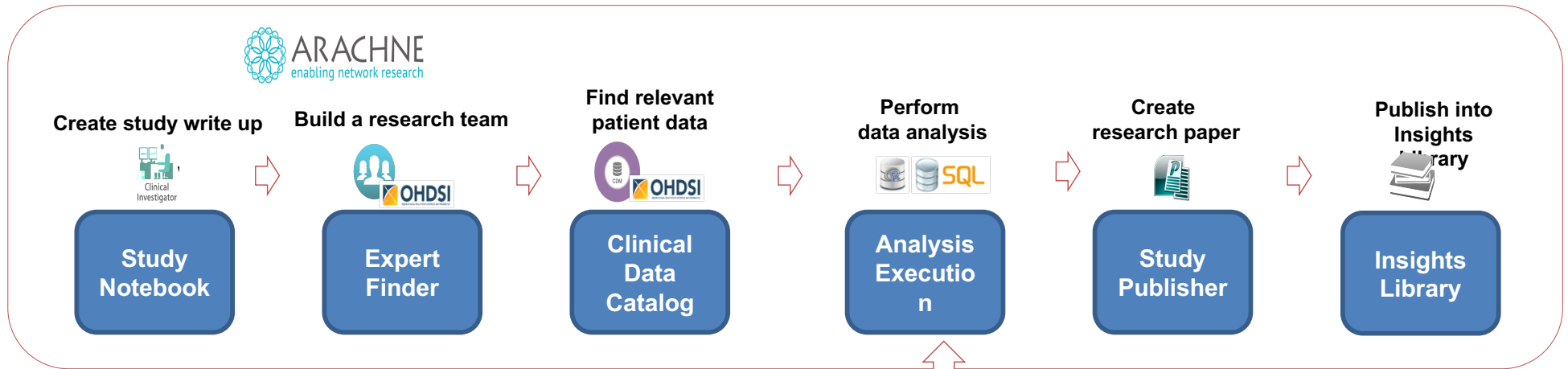
#### Persons With Continuous Observation By Month





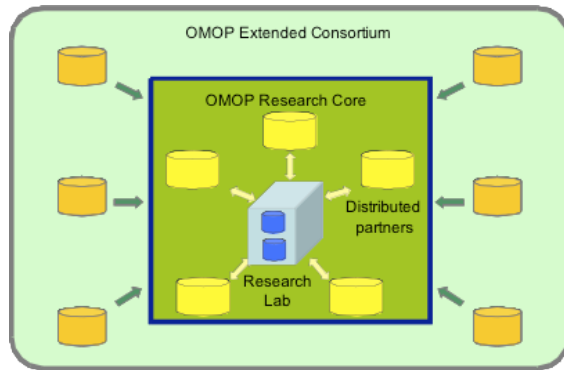


# ARACHNE Research Collaboration Network and Workflow Suite

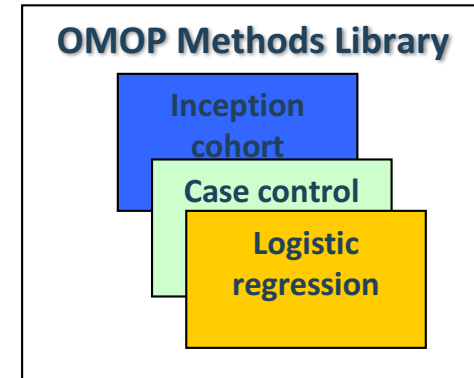
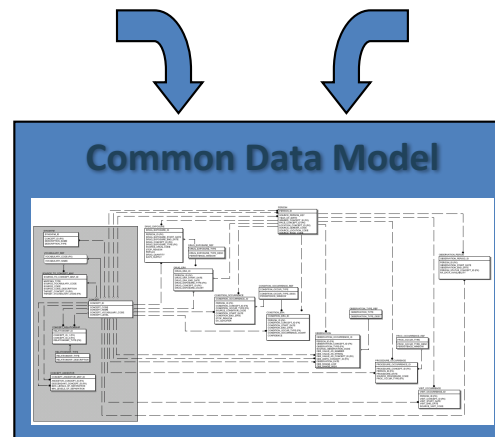




# Common Data Model



- 10 data sources

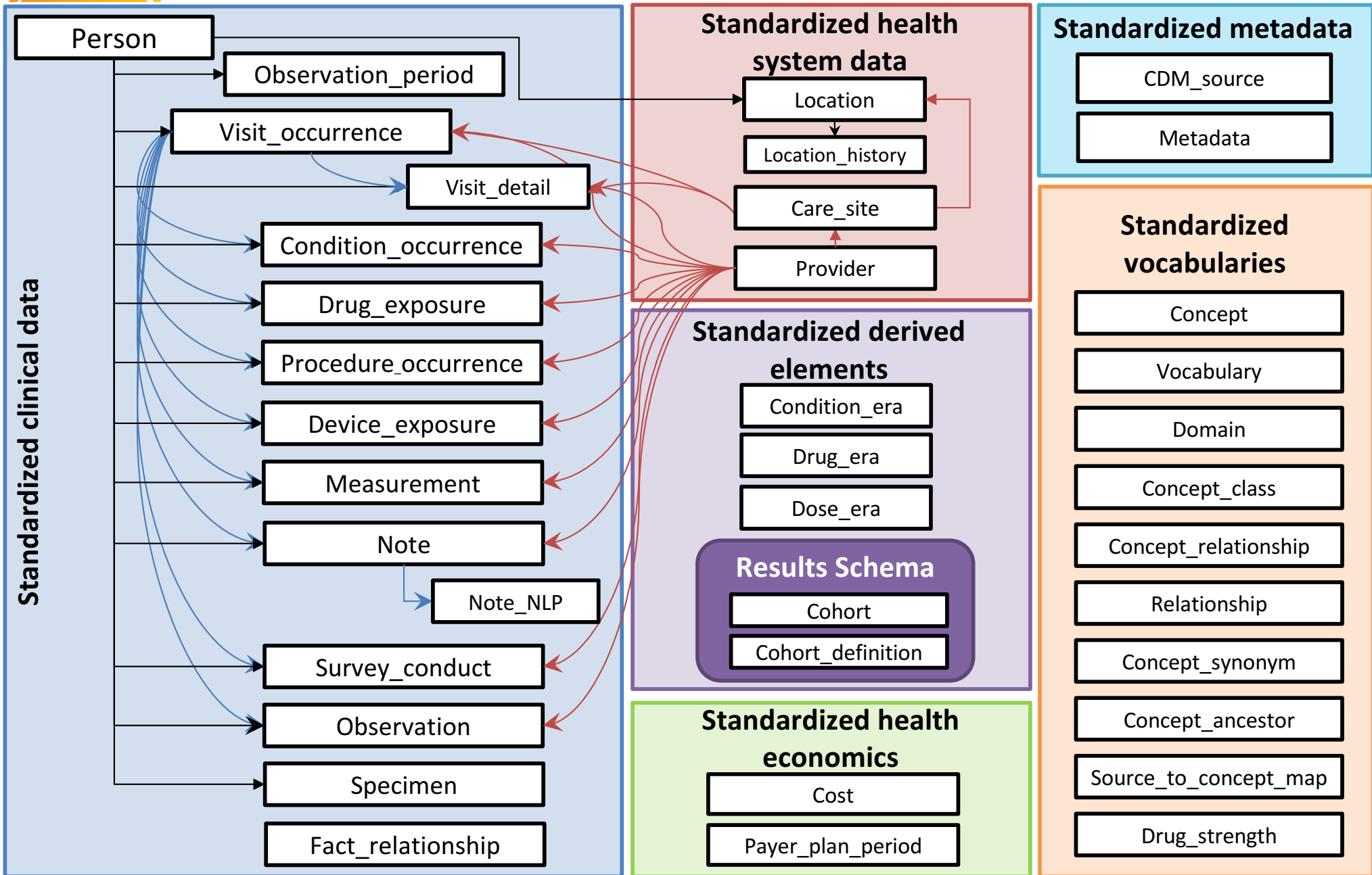


- 14 methods

Red	Blue	White	Blue	Blue	Blue	White	White	Blue
Blue	Blue	Blue	Red	Blue	Blue	Blue	White	Blue
White	Blue	Red	White	Blue	Blue	Blue	White	Blue
White	Blue	Blue	White	Blue	White	Blue	White	Red
Blue	Blue	Blue	White	Red	Blue	White	White	Blue
Green	White	Blue	White	Blue	Blue	Blue	White	White
White	Blue	Blue	Blue	Blue	Green	Blue	Red	Blue
White	Red	Blue	Blue	Blue	Blue	Blue	Blue	Blue
Blue	Blue	White	Blue	Blue	Blue	Red	Blue	White

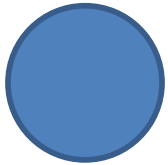


# CDM Version 6 Key Domains





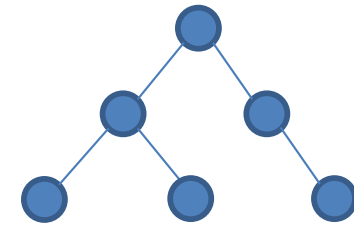
# Structure of OMOP Vocabulary



All content: concepts in  
**concept**



Direct relationships between  
concepts in  
**concept\_relationship**

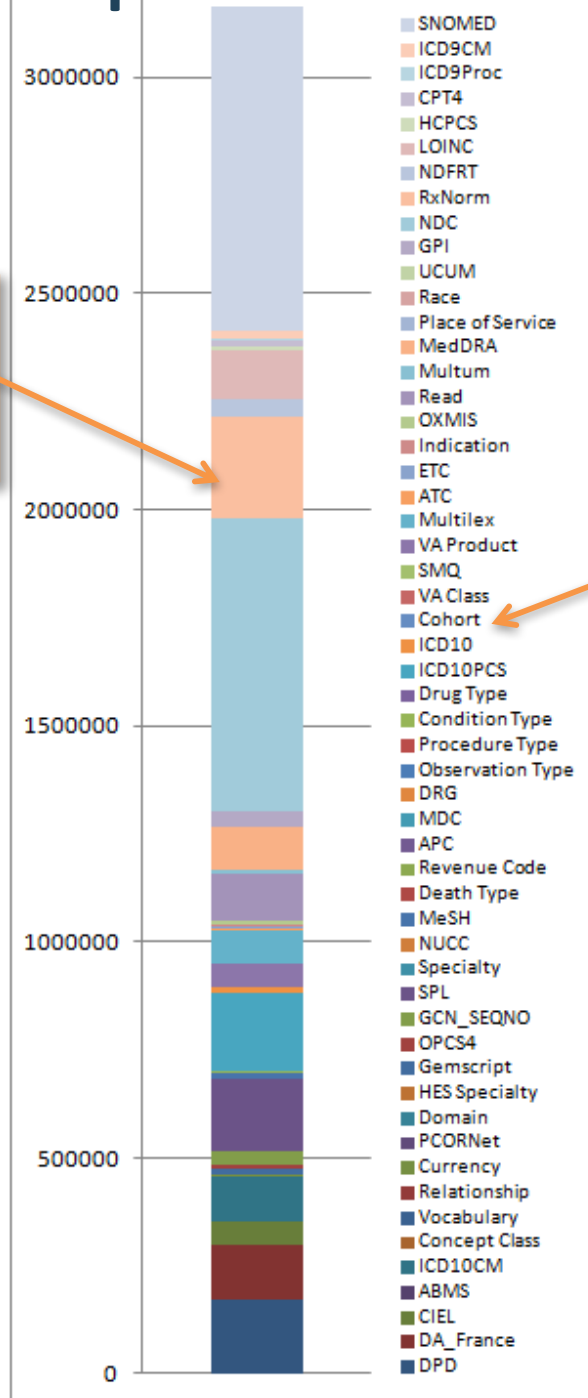


Multi-step hierarchical  
relationships pre-processed  
into  
**concept\_ancestor**



# Single Concept Reference Table

All vocabularies stacked up in one table



Vocabulary ID



# Dozens of schemes, formats, rules

## LOINC\_248\_MULTI-AXIAL\_HIERARCHY.CSV

PATH_TO_ROOT	SEQUENC	IMMEDIATE_PARENT	CODE	CODE_TEXT
	1		LP31755-9	Microbiology
LP31755-9	1	LP31755-9	LP14559-6	Microorganism
LP31755-9.L	1	LP14559-6	LP98185-9	Bacteria
LP31755-9.L	1	LP98185-9	LP14082-9	Bacteria

loinc.csv

LOINC_NL	COMPONENT	PROPERTY	TIME_ASPECT	SYSTEM	SCALE_TYP	METHOD_TYP	CLASS	SOURCE	DATE_LAST_CH	CHNG_TYP	COMM
LP31755-9.	10454-7	Xylose^2H post 25 g xylose PO	MCnc	Pt	Ser/Plas	Qn	CHAL	SH	19961220	ADD	
LP31755-9.	10455-4	Xylose^30M post 25 g xylose PO	MCnc	Pt	Ser/Plas	Qn	CHAL	SH	19961220	ADD	
LP31755-9.	10456-2	Xylose^post 6H CFst	MCnc	Pt	Ser/Plas	Qn	CHAL	SH	19961220	ADD	
LP31755-9.	10457-0	Actin Ag					PATH	SH;DL-M	20060706	MIN	
LP31755-9.	10458-8	Alkaline phosphatase.placer					PATH	DL-M	20060706	MIN	

## CMS32\_DESC\_LONG\_SHORT\_DX.xlsx

DIAGNOSIS CODE	LONG DESCRIPTION	SHORT DESCRIPTION
0010	Cholera due to vibrio cholerae	Cholera d/t vib cholerae
0011	Cholera due to vibrio cholerae el tor	Cholera d/t vib el tor
0019	Cholera, unspecified	Cholera NOS
0020	Typhoid fever	Typhoid fever
0021	Paratyphoid fever A	Paratyphoid fever a
0022	Paratyphoid fever B	Paratyphoid fever b
0023	Paratyphoid fever C	Paratyphoid fever c
0029	Paratyphoid fever, unspecified	Paratyphoid fever NOS
0030	Salmonella gastroenteritis	Salmonella enteritis
0031	Salmonella septicemia	Salmonella septicemia
00320	Localized salmonella infection, unspecified	Local salmonella inf NOS
00321	Salmonella meningitis	Salmonella meningitis
00322	Salmonella pneumonia	Salmonella pneumonia
00323	Salmonella arthritis	Salmonella arthritis
00324	Salmonella osteomyelitis	Salmonella osteomyelitis
00329	Other localized salmonella infections	Local salmonella inf NEC

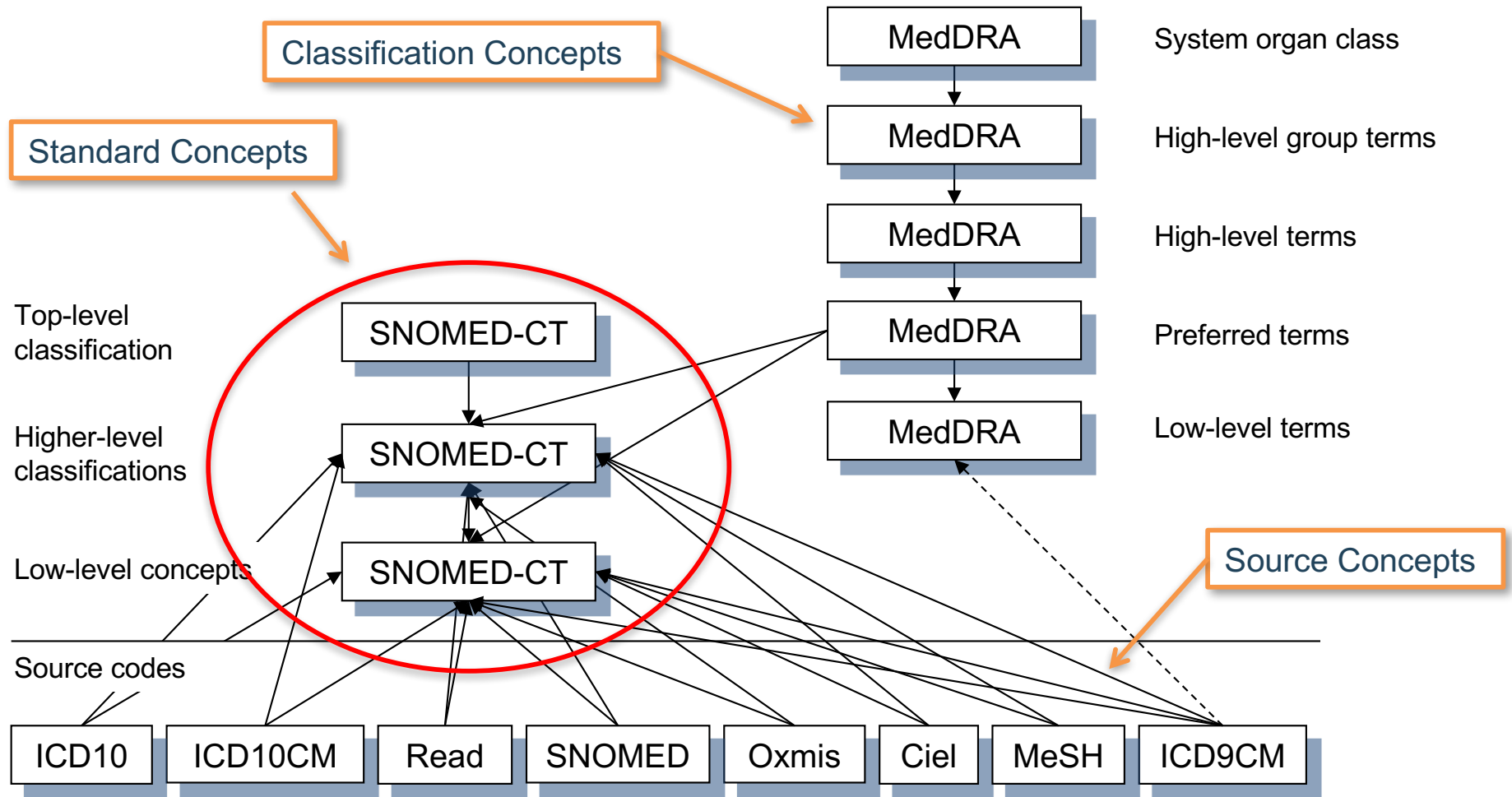


# Vocabulary Goals

- ✓ **Domains:** Every Standard Concept belongs to the right Domain
- **No duplicates:** For every entity exists one Standard Concept
- **Comprehensive:** For every Domain exists a complete finite set of Concepts covering all possible entities in this domain
- **Hierarchy:** All Concepts are connected through a comprehensive hierarchy
- **Mapping:** For every existing code in a vocabulary there is a map to a Standard Concept or a map to 0



# Condition Concepts





# Why are we mapping?



## LANGUAGES

Supporting language learning and linguistic diversity

European Commission > Languages > Policy > Linguistic diversity

### Official languages of the EU

What is it?

The European Union has 24 official and working languages. They are:

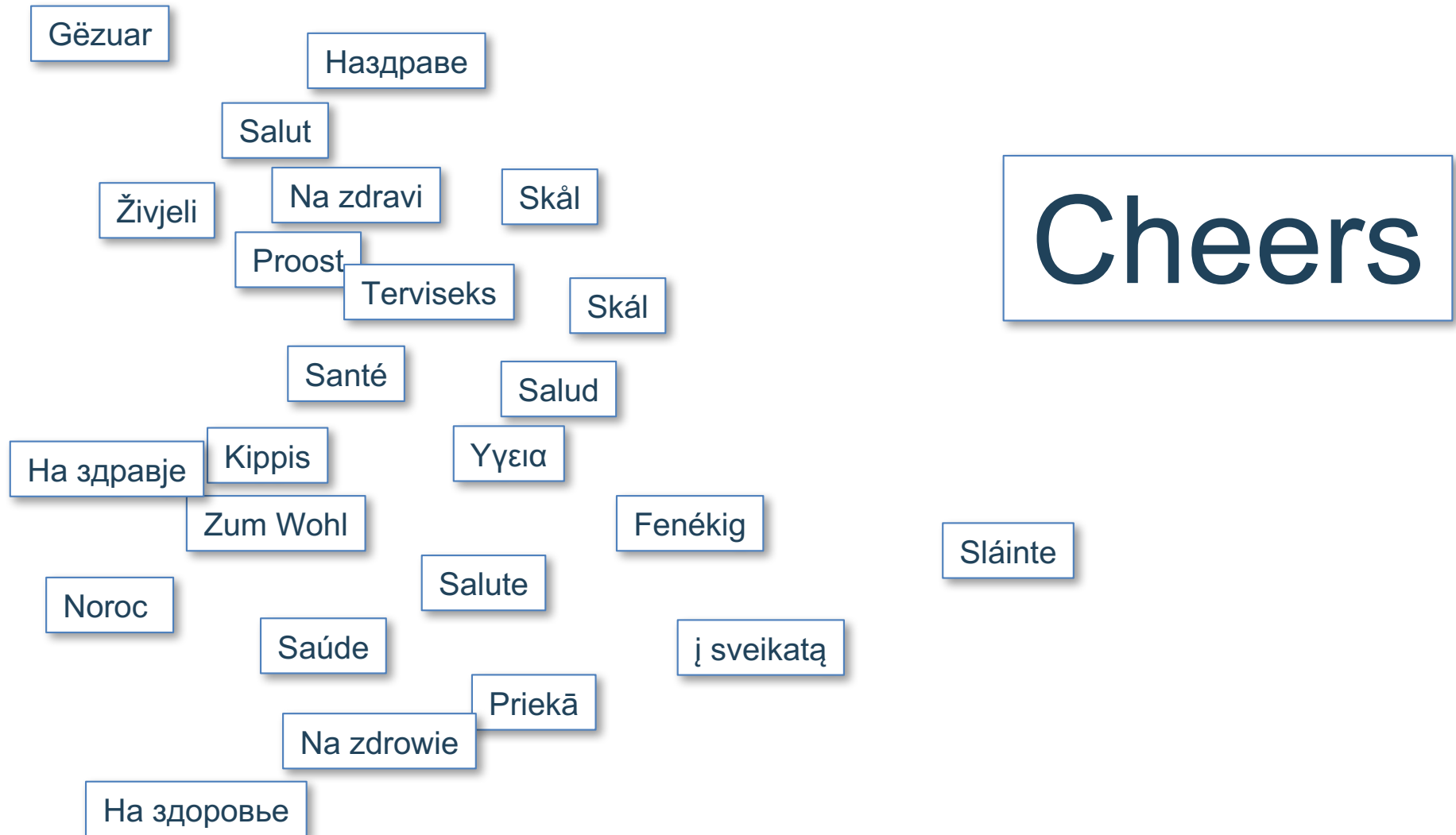
Bulgarian	French	Maltese
Croatian	German	Polish
Czech	Greek	Portuguese
Danish	Hungarian	Romanian
Dutch	Irish	Slovak
English	Italian	Slovenian
Estonian	Latvian	Spanish
Finnish	Lithuanian	Swedish

What is the Commission doing?

With a permanent staff of 1,750 linguists and 600 support staff, the Commission has one of the largest translation services in the world, bolstered by a further 600 full-time and 3,000 freelance interpreters.



# How many different ways do you express one meaning?





# Mapping = Translating

## Step 1. Lookup the Source Concept

```
SELECT * FROM concept WHERE concept_code = '427.31';
```

CONCEPT_ID	CONCEPT_NAME	DOMAIN_ID	VOCABULARY_ID	CONCEPT_CLASS_ID	STANDARD_CONCEPT	CONCEPT_CODE
44821957	Atrial fibrillation	Condition	ICD9CM	5-dig billing code		427.31

## Step 2. Translate to Standard

```
SELECT * FROM concept_relationship WHERE concept_id_1 = 44821957  
AND relationship_id = 'Maps to';
```

CONCEPT_ID_1	CONCEPT_ID_2	RELATIONSHIP_ID	VALID_START_DATE	VALID_END_DATE	INVALID_REASON
44821957	313217	Maps to	01-Jan-1970	31-Dec-2099	

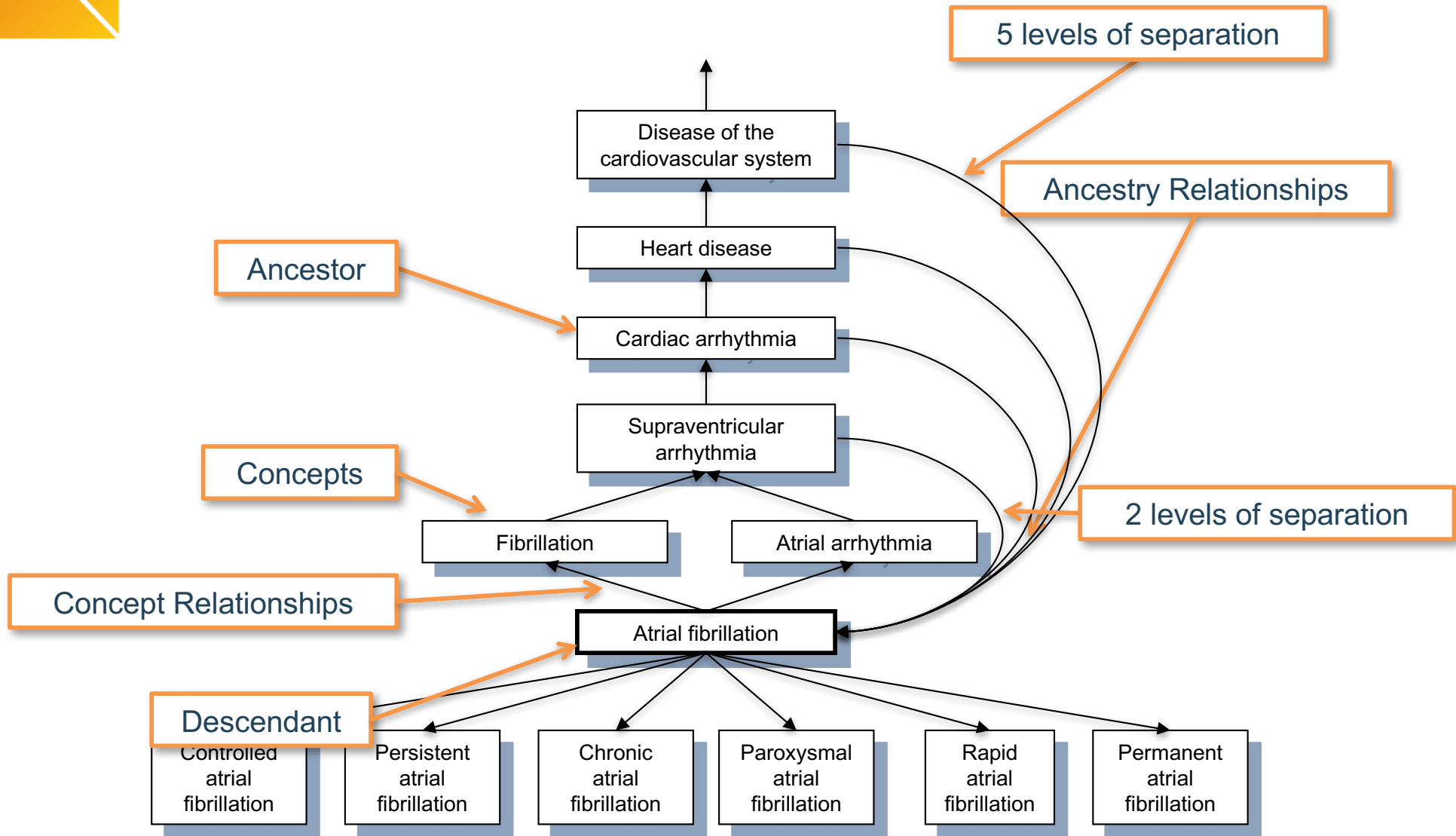
## Step 3. Check out the translated Concept

```
SELECT * FROM concept WHERE concept_id = 313217;
```



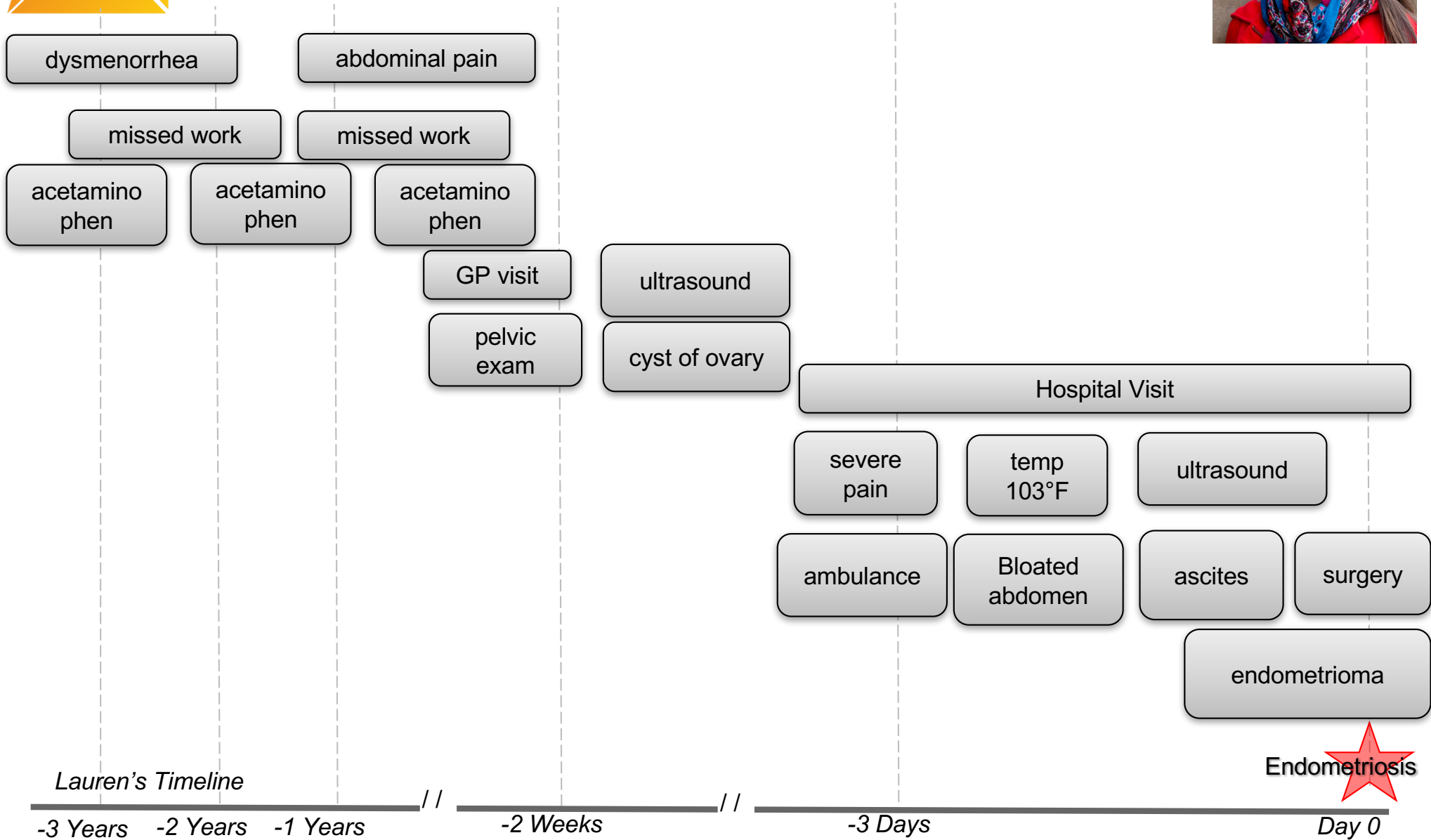


# Ancestry Relationships: Higher-Level Relationships





# What data do we have?





# Examples of how Researchers get Lauren's data?

- Health Insurance Claim Form (HCFA-1500)
- Universal Billing form (UB-92)

24.	A						B	C	D		E	F		G	H	I	J	K	PHYSICIAN OR SUPPLIER INFORMATION
	DATE(S) OF SERVICE From			To								Place of Service	Type of Service	PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)	DIAGNOSIS CODE	\$ CHARGES	DAYS OR UNITS	EPSDT Family Plan	
	MM	DD	YY	MM	DD	YY			CPT/HCPCS	MODIFIER									
1																			
2																			
3																			
4																			
5																			
6																			



# Examples of how Researchers get Lauren's data?

- Health Insurance Claim Form (HCFA-1500)
- Universal Billing form (UB-92)
- Prescriptions

<b>R</b>	PATIENT'S NAME <u>Lauren</u>	AGE <u>28</u>
	ADDRESS <u>UK</u>	DATE <u>May 29</u>
<i>Antibiotic 20 mg</i>		
<i>1 tab PO t.i.d X 7 days</i>		
<i>refills 0</i>		
OFFICE ADDRESS _____	DEA NO. _____	
REPETATUR YES <input type="checkbox"/> NO <input type="checkbox"/> TIMES _____	PALC NO. _____	
ITEM #52925		



# Examples of how Researchers get Lauren's data?

- Health Insurance Claim Form (HCFA-1500)
- Universal Billing form (UB-92)
- Prescriptions
- Doctors notes

Patient: Lauren

Date of Procedure: 12-March

Surgeon: Dr. Patrick Ryan

Assistant: Dr. Erica Voss

Procedure: Endometrial biopsy

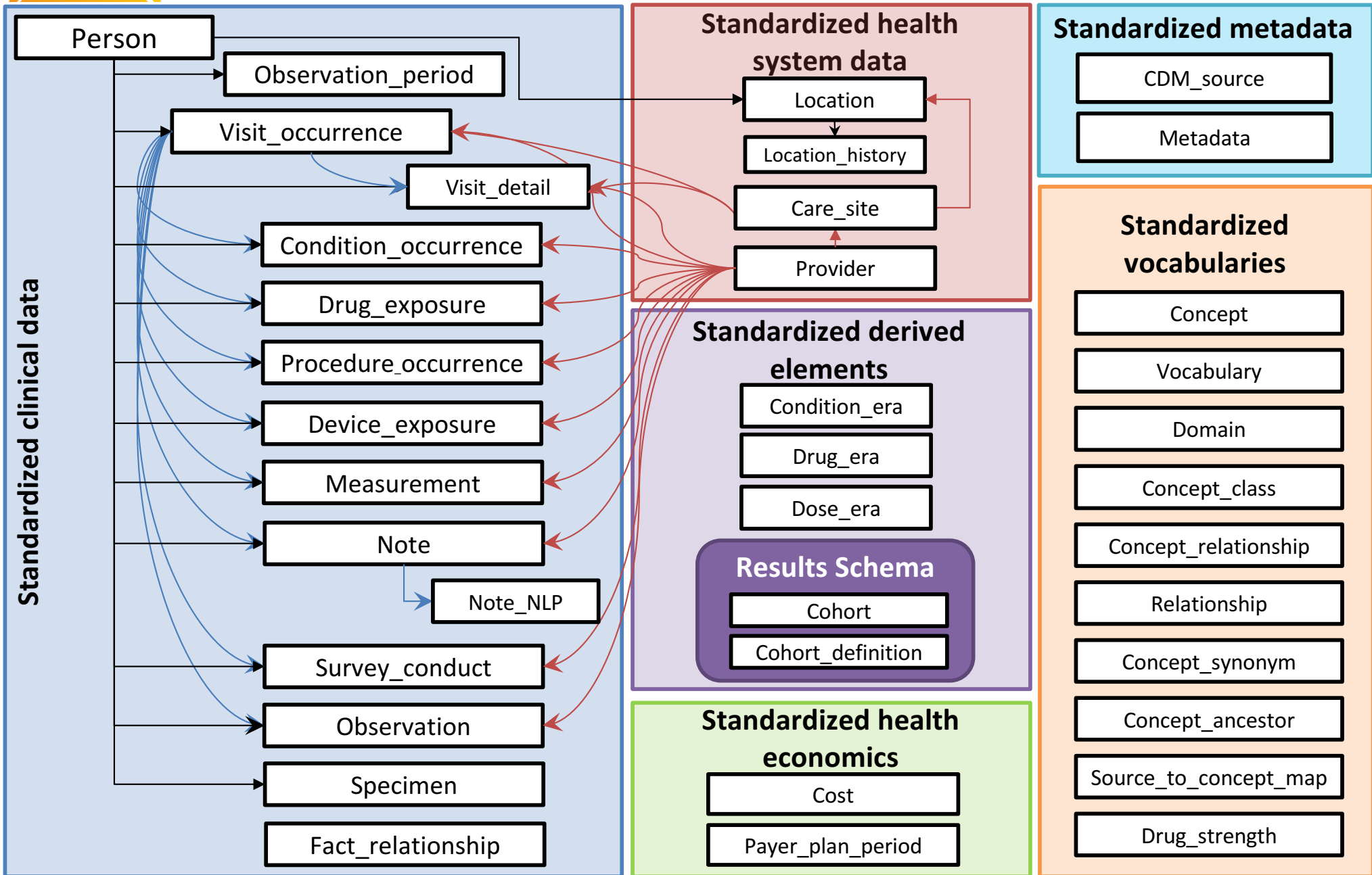
Operative Summary: Endometrial biopsy performed with sterile technique. Adequate sample.

Presence of endometrial tissues outside the uterus.





# CDM Version 6 Key Domains





# PERSON



COLUMN	EXAMPLE
person_id	123456 <i>Lauren's ID</i>
gender_concept_id	8532 <i>Female</i>
year_of_birth	1982
month_of_birth	NULL
day_of_birth	NULL
race_concept_id	8527 <i>White</i>
person_source_value	123456
gender_source_value	F
race_source_value	W



# OBSERVATION\_PERIOD



COLUMN	EXAMPLE
observation_period_id	1
person_id	123456 <i>Lauren's ID</i>
observation_period_start_date	2000-01-01
observation_period_end_date	2010-12-31

COLUMN	EXAMPLE
observation_period_id	2
person_id	123456 <i>Lauren's ID</i>
observation_periods_start_date	2012-01-01
observation_periods_start_date	2013-12-31



# VISIT\_OCCURRENCE



COLUMN	EXAMPLE
visit_occurrence_id	1
person_id	123456 <i>Lauren's ID</i>
visit_start_date	2008-04-07
visit_end_date	2008-04-07
visit_concept_id	9202 <i>Outpatient Visit</i>
visit_source_value	OP

COLUMN	EXAMPLE
visit_occurrence_id	2
person_id	123456 <i>Lauren's ID</i>
visit_start_date	2008-04-21
visit_end_date	2008-04-26
visit_concept_id	9201 <i>Inpatient Visit</i>
visit_source_value	IP



# CONDITION\_OCCURRENCE



COLUMN	EXAMPLE
condition_occurrence_id	1
person_id	123456 <i>Lauren's ID</i>
condition_concept_id	433527 <i>Endometriosis</i>
condition_start_date	2008-04-24
condition_type_concept_id	38000183 <i>Inpatient detail - primary</i>
visit_occurrence_id	2
condition_source_value	6171 <i>ICD9, missing decimal</i>
condition_source_concept_id	44832501 <i>Endometriosis of ovary</i>



# DRUG\_EXPOSURE



COLUMN	EXAMPLE
drug_exposure_id	1
person_id	123456 <i>Lauren's ID</i>
drug_concept_id	40162494 <i>Acetaminophen 500 MG / Hydrocodone Bitartrate 5 MG Oral Tablet</i>
drug_exposure_start_date	2007-02-01
drug_exposure_end_date	2007-02-08 <i>Drug_exposure_start_date + days_supply</i>
verbatim_end_date	NULL
drug_type_concept_id	38000183 <i>Prescription dispensed in pharmacy</i>
refills	0
quantity	14
days_supply	7
drug_source_value	54348001301 <i>NDC 11-digit code</i>
drug_source_concept_id	45904353 <i>Acetaminophen 500 MG / Hydrocodone Bitartrate 5 MG Oral Tablet</i>



# PROCEDURE\_OCCURRENCE



COLUMN	EXAMPLE
procedure_occurrence_id	1
person_id	123456 <i>Lauren's ID</i>
procedure_concept_id	2211740 <i>Ultrasound, abdominal, real time with image documentation; complete</i>
procedure_date	2008-04-08 <i>complete</i>
procedure_type_concept_id	38000267 <i>Outpatient detail - 1st position</i>
visit_occurrence_id	1
procedure_source_value	76700 <i>CPT4</i>
procedure_source_concept_id	2211740 <i>Ultrasound, abdominal, real time with image documentation; complete</i>



# MEASUREMENT



COLUMN	EXAMPLE
measurement_id	1
person_id	123456 <i>Lauren's ID</i>
measurement_concept_id	3020891 <i>Body temperature</i>
measurement_date	2008-04-21
measurement_type_concept_id	44818701 <i>From physical examination</i>
value_as_number	103
unit_concept_id	9289 <i>Degree Fahrenheit</i>
measurement_source_value	8310-5 <i>LOINC</i>
measurement_source_concept_id	3020891 <i>Body temperature</i>





# OBSERVATION

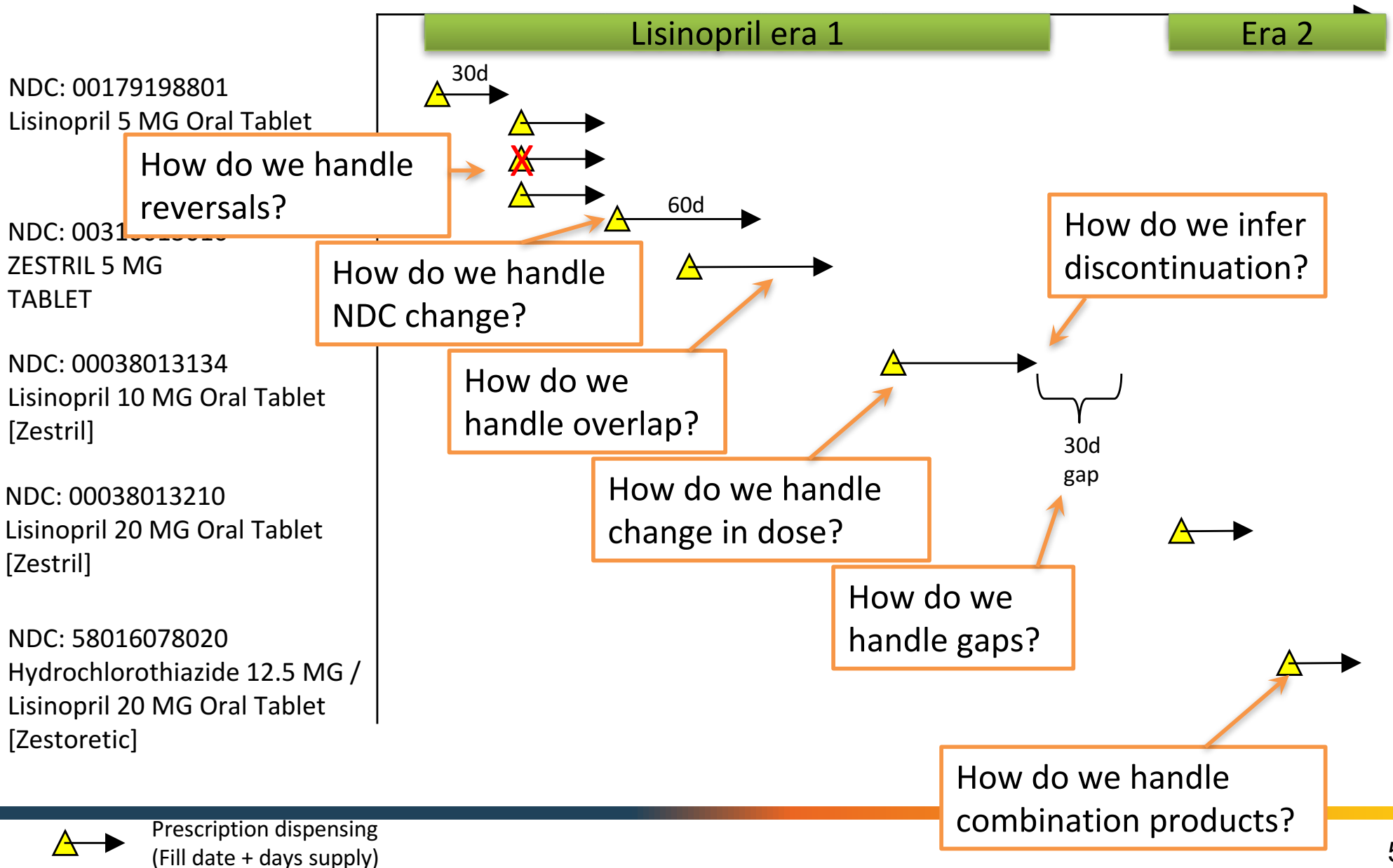


COLUMN	EXAMPLE
observation_id	1
person_id	123456 <i>Lauren's ID</i>
observation_concept_id	0 <i>No matching concept</i>
observation_date	2006-01-20
observation_type_concept_id	44814721 <i>Patient reported</i>
value_as_number	8
value_as_string	Work Hours Missed
observation_source_value	Work Hours Missed
observation_source_concept_id	0 <i>No matching concept</i>



# Illustrating inferences needed within longitudinal pharmacy claims data for one patient

## Person Timeline





# CDM Tables Not Covered in Detail



- VISIT\_DETAIL
- SPECIMEN
- DEATH
- DEVICE\_EXPOSURE
- NOTE
- NOTE\_NLP
- FACT\_RELATIONSHIP
- LOCATION
- CARE\_SITE
- PROVIDER
- PAYER\_PLAN\_PERIOD
- COST
- COHORT
- COHORT\_ATTRIBUTES
- CONDITION\_ERA
- DOSE\_ERA
- CDM\_SOURCE



# Standards

- Patients without transaction
- Cleaning dirty data
  - Patient IDs reused
  - Bogus code records (e.g. '000')
- How to handle tobacco information



THEMIS



# CDM Version Control

- Working group meets once a month to discuss proposed changes to the CDM
- All CDM documentation, versions, and proposals located on GitHub
  - <https://github.com/OHDSI/CommonDataModel>
  - Proposals tracked and discussed as GitHub issues
- Meeting information can be found on the working group [wiki page](#)
- Please contact Clair Blacketer ([mblack@its.jnj.com](mailto:mblack@its.jnj.com)) for more information



**OHDSI generates  
Evidence**





# Proceedings of the National Academy of Sciences, 2016



COLLOQUIUM  
PAPER

## Characterizing treatment pathways at scale using the OHDSI network

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Edited by Richard M. Shiffrin, Indiana University, Bloomington, IN, and approved April 5, 2016 (received for review June 14, 2015)

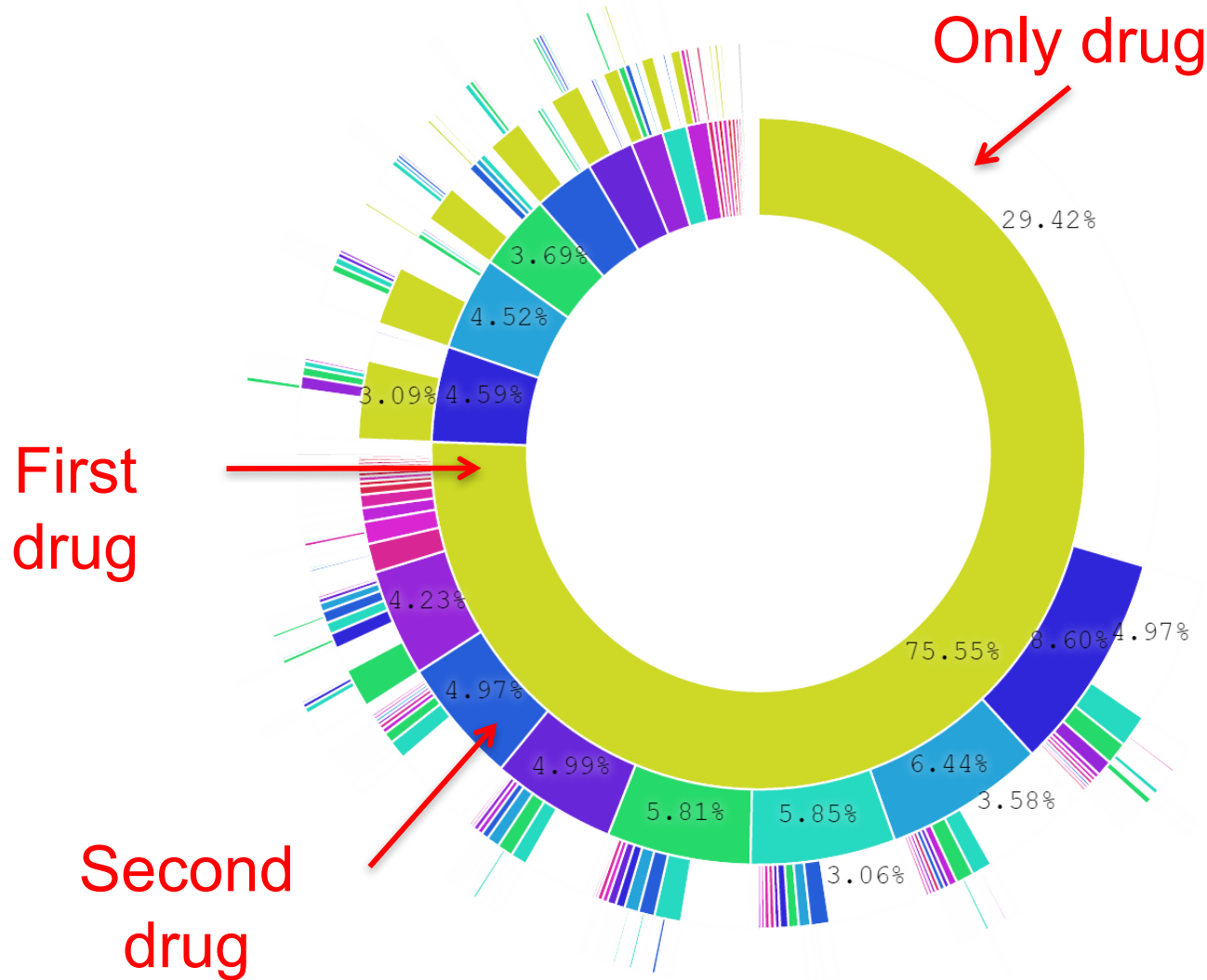
Observational research promises to complement experimental research by providing large, diverse populations that would be infeasible for an experiment. Observational research can test its own clinical hypotheses, and observational studies also can contribute to the design of experiments and inform the generalizability of experimental research. Understanding the diversity of populations

Without sufficiently broad databases available in the first stage, randomized trials are designed without explicit knowledge of actual disease status and treatment practice. Literature reviews are restricted to the population choices of previous investigations, and pilot studies usually are limited in scope. By exploiting the [ClinicalTrials.gov](http://ClinicalTrials.gov) national trial registry (9) and electronic health



# Treatment pathways for diabetes

T2DM : All databases

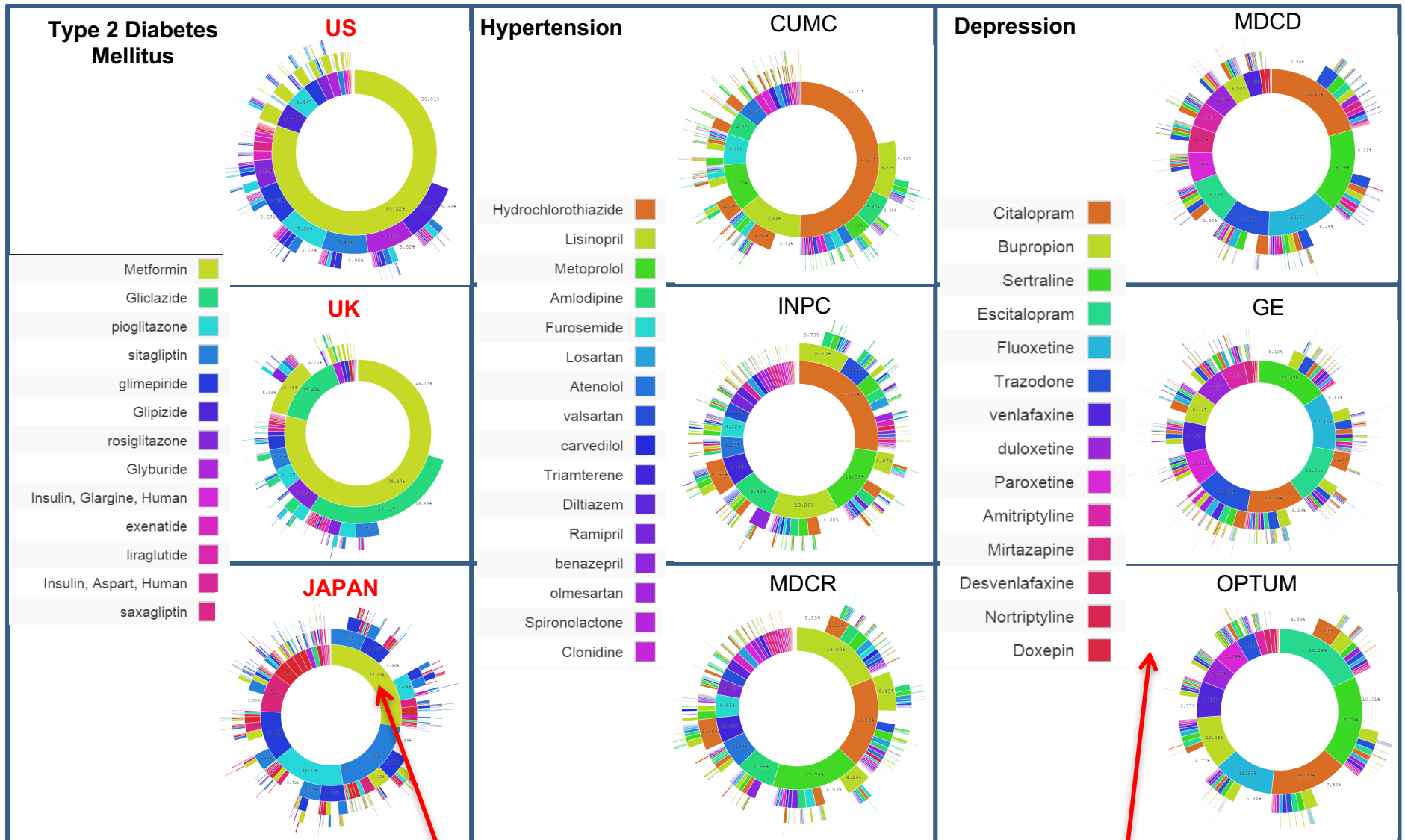


Metformin	
pioglitazone	
sitagliptin	
Glipizide	
glimepiride	
Gliclazide	
Glyburide	
rosiglitazone	
Insulin, Glargine, Human	
exenatide	
Insulin, Aspart, Human	
liraglutide	
saxagliptin	
Insulin, Lispro, Human	
Glucose	
Insulin, Isophane, Human	





# Heterogeneity in treatments



Japan differs in use of Metformin (due to genetics)

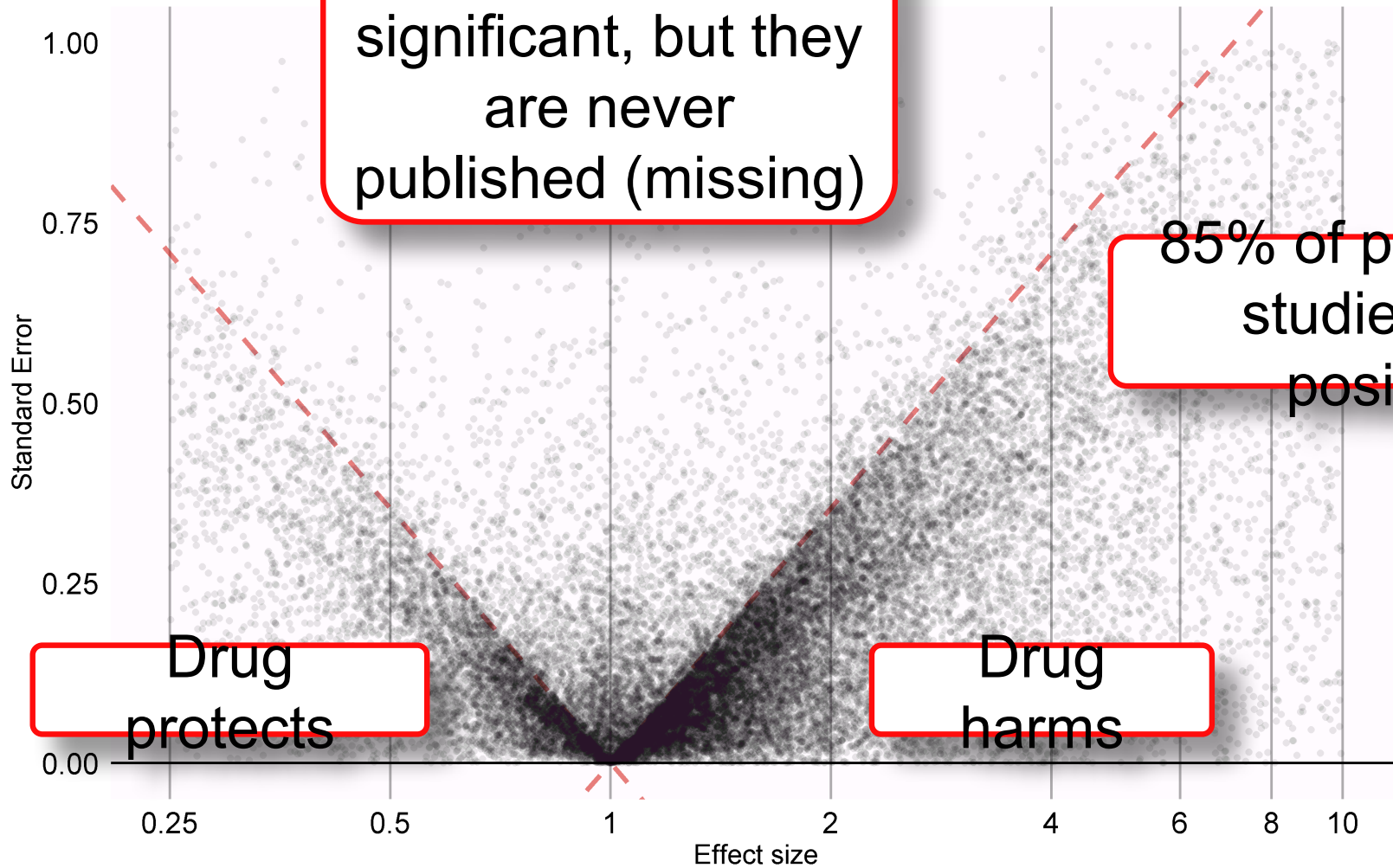
No agreement on depression



# The current literature is severely biased

In reality, most results are not significant, but they are never published (missing)

85% of published studies are positive



Drug protects

Drug harms

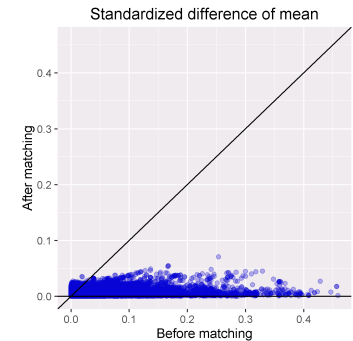
29,982 estimates  
11,758 papers



# OHDSI's reproducible research

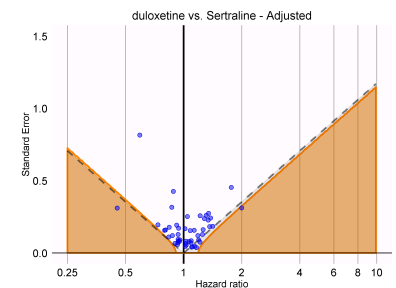
## 1. Address confounding that is measured

- Propensity stratification



## 2. Address unmeasured confounding

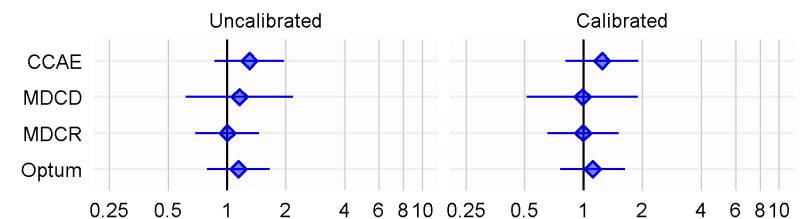
- Negative controls



## 3. Multiple databases, locations, practice types

- Exploit international OHDSI network

## 4. Open: publish all





## 5. Run 17,000 studies at once

Duloxetine vs. Sertraline for these 22 outcomes:

Acute liver injury	Hypotension
Acute myocardial infarction	Hypothyroidism
Alopecia	Insomnia
Constipation	Nausea
Decreased libido	Open-angle glaucoma
Delirium	Seizure
Diarrhea	Stroke
Fracture	Suicide and suicidal ideation
Gastrointestinal hemorrhage	Tinnitus
Hyperprolactinemia	Ventricular arrhythmia and sudden cardiac death
Hyponatremia	Vertigo

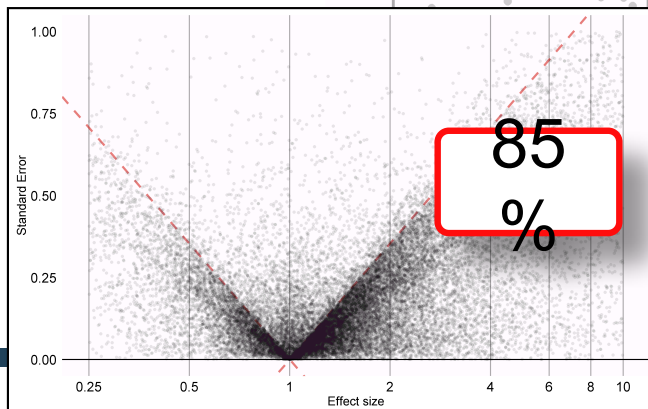
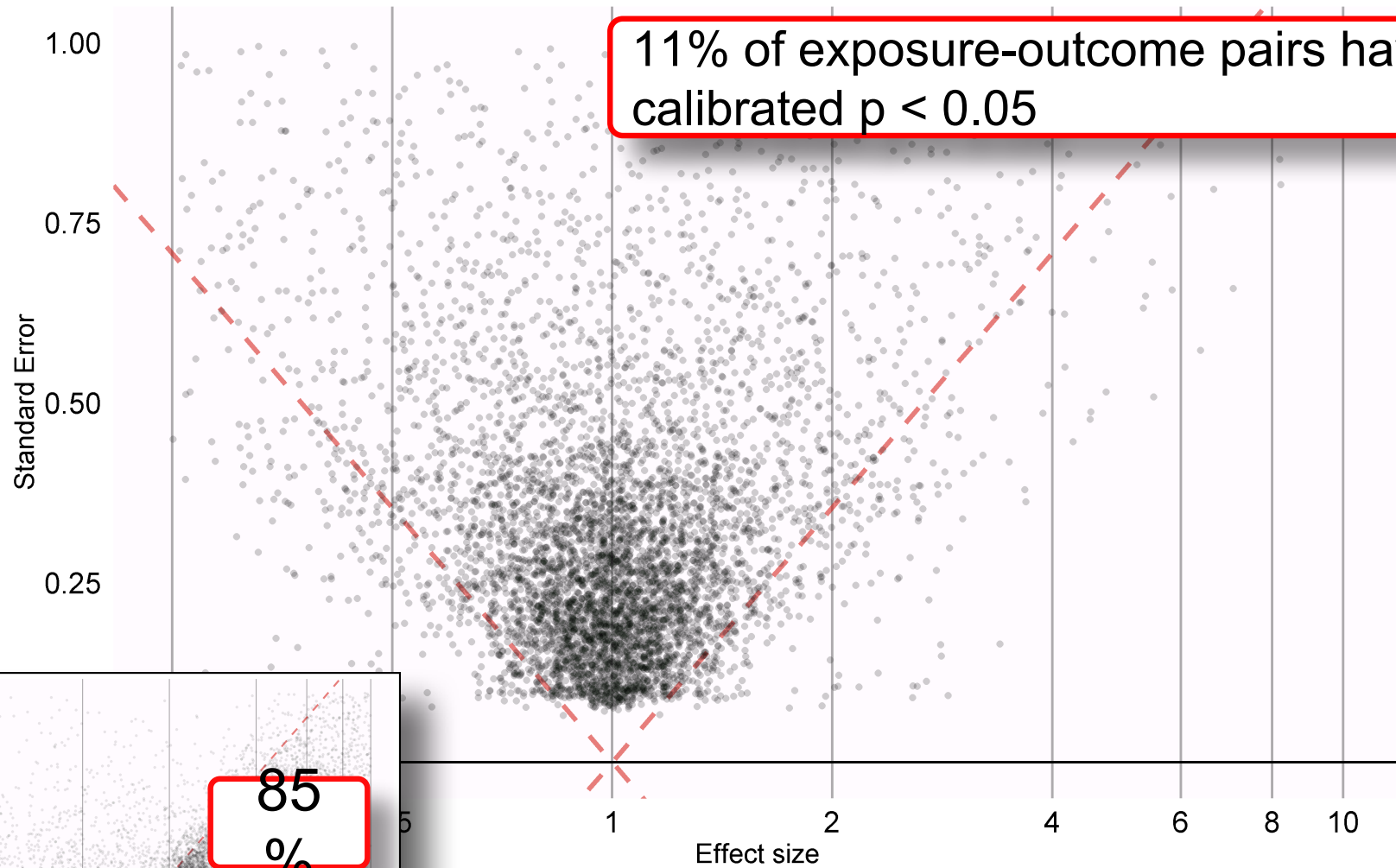


# Many treatments at once

Type	Class	Treatment
Drug	Atypical	Bupropion
Drug	Atypical	Mirtazapine
Procedure	ECT	Electroconvulsive therapy
Procedure	Psychotherapy	Psychotherapy
Drug	SARI	Trazodone
Drug	SNRI	Desvenlafaxine
Drug	SNRI	duloxetine
Drug	SNRI	venlafaxine
Drug	SSRI	Citalopram
Drug	SSRI	Escitalopram
Drug	SSRI	Fluoxetine
Drug	SSRI	Paroxetine
Drug	SSRI	Sertraline
Drug	SSRI	vilazodone
Drug	TCA	Amitriptyline
Drug	TCA	Doxenilin



# OHDSI's results: less bias





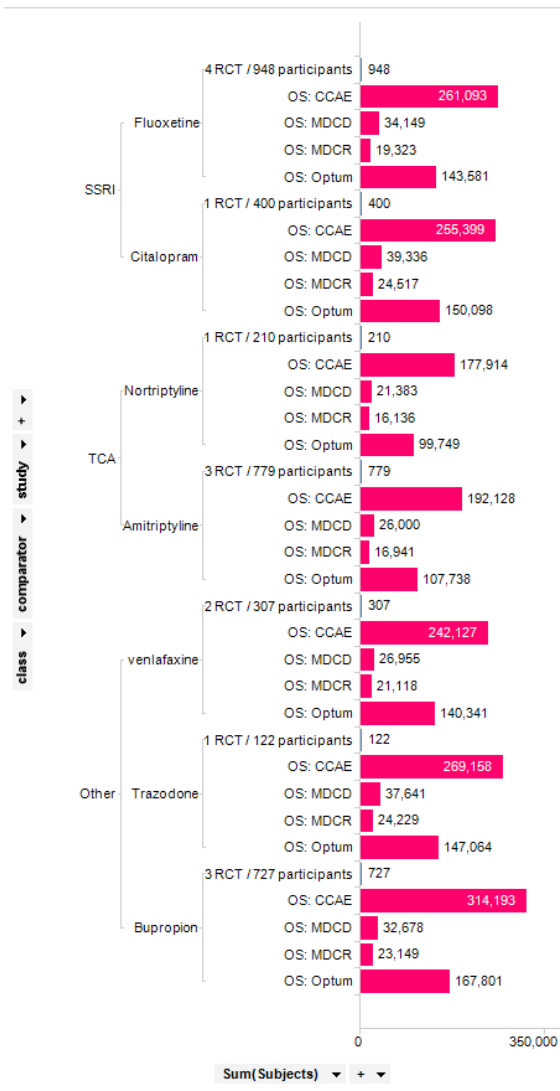
# Benefit and Harm of 2nd-generation Antidepressants

	Citalopram	Escitalopram	Fluoxetine	Paroxetine	Sertraline	Vilazodone	Desvenlafaxine	Duloxetine	Venlafaxine	Amitriptyline	Doxepin	Nortriptyline	Bupropion	Mirtazapine	Trazodone
Outcome	SSRI					SNRI				TCA			Other Drugs		
Acute liver injury	Advers	Advers	Advers	Advers	Reacti		Overd	Warnin	Overd	Advers		Precau	Reacti	Reacti	
Acute myocardial infarction	Advers	Advers		Advers	Reacti		Reacti	Reacti		Advers		Advers	Reacti	Reacti	Reacti
Alopecia	Advers	Advers	Advers	Advers	Reacti		Reacti		Reacti	Advers	Advers	Advers	Reacti	Reacti	Reacti
Constipation	Advers	Advers	Advers	Advers	Reacti		Reacti	Reacti	Reacti	Precau	Advers	Advers	Reacti	Reacti	Reacti
Decreased libido	Advers	Advers	Advers	Advers	Reacti	Reacti	Reacti	Reacti	Reacti	Advers	Advers	Advers	Reacti	Reacti	Reacti
Delirium	Advers	Advers	Overd	Advers	Overd	Warnin	Warnin	Warnin	Reacti	Precau		Warnin	Reacti	Reacti	
Diarrhea	Advers	Advers	Advers	Advers	Reacti	Reacti	Reacti	Reacti	Reacti	Advers	Advers	Advers	Reacti	Reacti	Reacti
Fracture				Precau				Warnin						Reacti	
Gastrointestinal hemorrhage	Advers	Advers	Warnin	Precau	Precau	Warnin	Warnin	Warnin	Warnin				Reacti		Warnin
Hyperprolactinemia	Advers	Advers	Advers	Advers	Reacti		Reacti	Reacti	Reacti						
Hyponatremia	Precau	Warnin	Warnin	Precau	Precau	Warnin	Warnin	Warnin	Warnin					Precau	Warnin
Hypotension	Advers	Advers	Advers	Advers	Reacti		Reacti	Warnin	Reacti	Advers	Advers	Advers	Reacti	Reacti	Warnin
Hypothyroidism	Advers			Advers	Reacti			Reacti						Reacti	
Insomnia	Advers	Advers	5.1	Advers	Reacti	Reacti	Reacti	Reacti	Reacti	Advers	Precau	Warnin	Reacti	Reacti	Reacti
Nausea	Advers	Advers	Advers	Advers	Reacti	Reacti	Reacti	Reacti	Reacti	Advers	Advers	Advers	Reacti	Reacti	Reacti
Open-angle glaucoma	Warnin	Warnin	Warnin	Warnin	Warnin	Warnin	Warnin	Warnin	Warnin	Precau		Warnin	Warnin	Warnin	Warnin
Seizure	Precau	Warnin	Warnin	Precau	Precau	Warnin	Warnin	Warnin	Warnin	Advers	Advers	Advers	Warnin	Precau	Warnin
Stroke	Advers	Advers	Advers	Advers	Reacti					Advers		Advers	Reacti		Reacti
Suicide and suicidal thoughts	Boxed	Boxed	Boxed	Boxed	Boxed	Boxed	Boxed	Boxed	Boxed	Boxed	Boxed	Boxed	Boxed	Boxed	Boxed
Tinnitus	Advers	Advers		Advers	Reacti		Reacti	Reacti	Reacti	Advers	Advers	Advers	Reacti	Reacti	Reacti
Ventricular arrhythmia	Warnin	Advers	Warnin	Advers	Reacti		Reacti	Reacti	Reacti	Advers	Advers	Advers		Warnin	Warnin
Vertigo	Advers	Advers	Overd	Advers	Reacti		Reacti	Reacti	Overd				Reacti	Reacti	Reacti

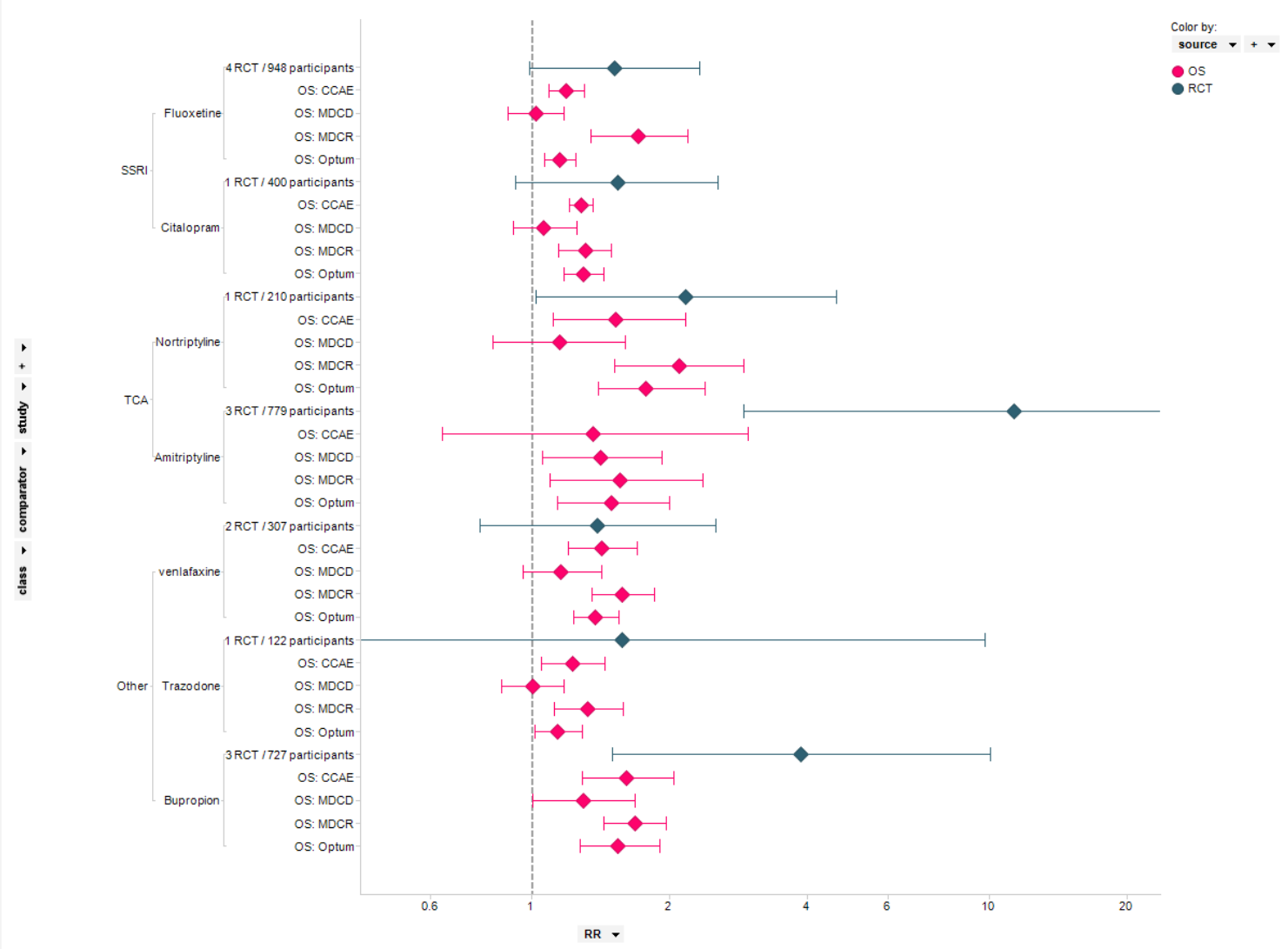


# Comparing RCT and observational results for effects of sertraline on diarrhea

Study population sizes (Target=Sertraline)



Population-level effect estimates (Target=Sertraline, Outcome=Diarrhea)







# Comparative effectiveness hypotheses from Gartleher et al

- Venlafaxine has higher risk of nausea than SSRI
  - No difference in nausea between duloxetine and paroxetine or fluoxetine
  - Sertraline has higher risk of diarrhea than comparators
  - Paroxetine has higher rate of sexual dysfunction than fluoxetine and sertraline.
  - Bupropion has lower incidence of sexual dysfunction than fluoxetine, paroxetine, and sertraline.
  - Trazodone increased risk of somnolence
-



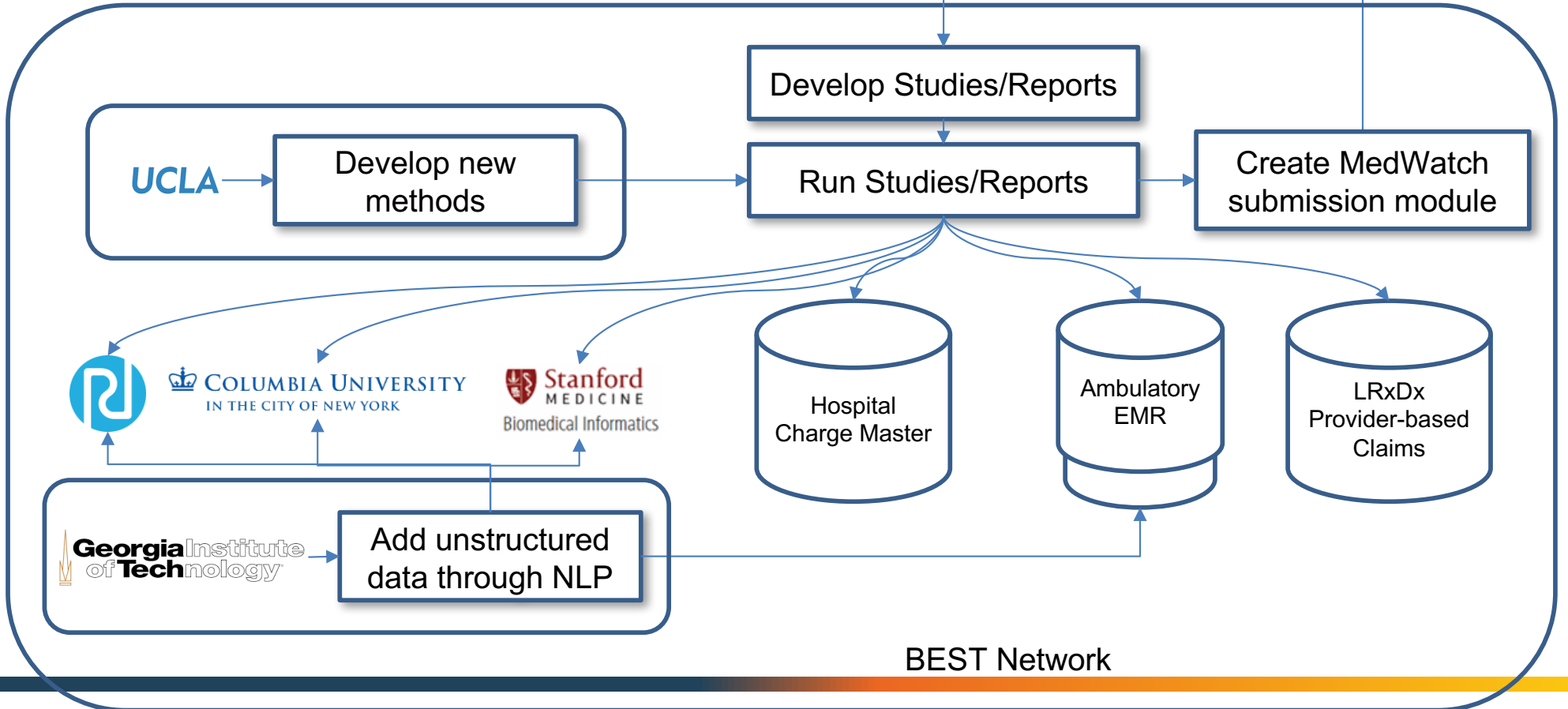
# FDA BEST Program



Report back

**62 studies:**

- Simple: Rapid queries
  - Medium complexity: cohort characterization
  - High complexity: safety, pharmacoepi
- AE Reports**





# Summary

- OHDSI is a public world-wide collaborative. Everybody can participate. It's free. There is no catch.
- You don't have to give the data away, but you need to standardize the data. The standard is strict. No shortcuts!
- When you do that, you get tools, methods, and a lot of new colleagues. People in the OHDSI community are nice and competent.
- You can do meaningful and scientifically high-quality network research



Join the Journey

<http://ohdsi.org>