





# Hands-on Workshop: Introduction to International Medical Data Standard OMOP CDM for Observational Research

21 September 2023













### https://bit.ly/omop-workshop-slide

เวลา	หัวข้อ	วัตถุประสงค์
09:00 – 09:15	ลงทะเบียน	
09:15 – 09:30	เปิดการอบรม และแนะนำภาพรวม โดย ผศ.ดร.ประพัฒน์ สุริยผล	
09:30 – 10:30	Introduction to OMOP CDM and OHDSI	ทำความรู้จักกับ OMOP CDM และ OHDSI
10:30 – 10:45	รับประทานอาหารว่าง (เช้า)	
10:45 – 11:15	Inspiring Experience from Singapore	เห็นตัวอย่างการนำ OMOP CDM และ OHDSI Tools ไปใช้ในงาน
	โดย Asst. Prof. Mengling 'Mornin' Feng	วิจัย และความร่วมมือจากภาคส่วนต่าง ๆ ในประเทศเพื่อนบ้าน
11:15 – 12:00	OHDSI Tools: Athena & Atlas	สามารถใช้งานเครื่องมือ Athena และ Atlas
12:00 – 13:00	รับประทานอาหารกลางวัน	
13:00 – 14:30	OHDSI Tools: Cohort Definition & Characterization	สามารถกำหนดกลุ่ม Cohort เพื่อการวิจัย และวิเคราะห์เชิงสถิติ ต่าง ๆ เบื้องต้น
14:30 – 14:45	รับประทานอาหารว่าง (บ่าย)	
14:45 – 15:45	OHDSI Tools: Patient-level Prediction	สามารถสร้างโมเดลการทำนายรายผู้ป่วยได้
15:45 – 16:15	Data Governance for Research	เข้าใจหลักการทางธรรมาภิบาลข้อมูล เกี่ยวกับการวิจัย
16:15 – 17:00	Networking Event (optional)	สร้างความรู้จักกันระหว่างผู้เข้าร่วมอบรม เพื่อการสร้างเครือข่าย วิจัยร่วมกันในอนาคต



# OHDSI, pronounced "Odyssey"

Observational Health Data Sciences and Informatics



[ https://www.worldhistory.org/odysseus/ ]

### Meet Your Today's Guide for OMOP/OHDSI Journey







### Natthawut 'Max' Adulyanukosol

MSc (cand.scient.) in Bioinformatics, BA Hons (Cantab) in Natural Sciences, CIPM

Deputy Director, Siriraj Informatics and Data Innovation Center (SiData+)

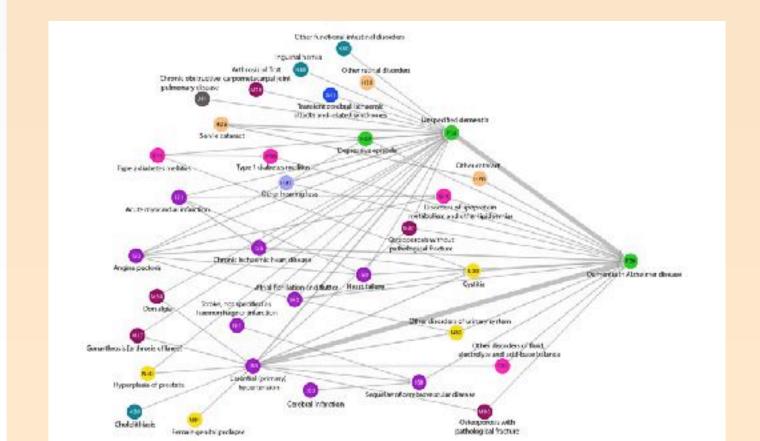
PhD Biomedical and Health Informatics Student, University of North Carolina at Chapel Hill, USA

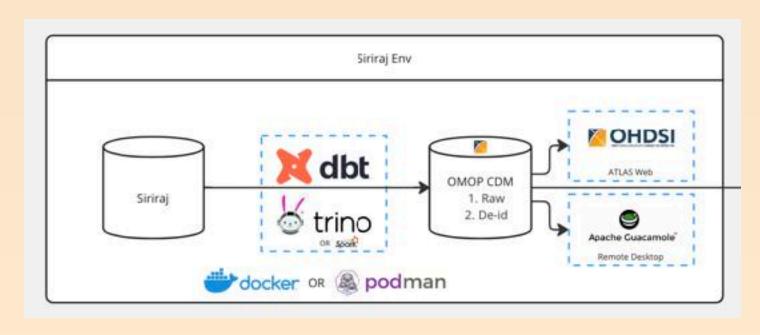
Past Work in Denmark

Disease Trajectory Model on Danish National Claims Registry

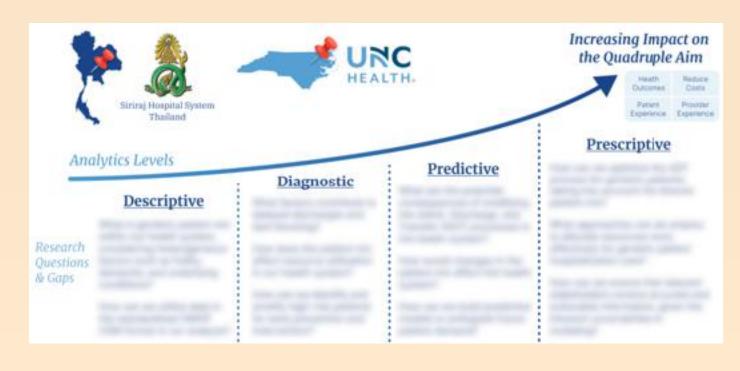
Ongoing Work in Thailand 
OMOP ETL Project Lead
at Siriraj & NHSO

Ongoing Work in USA ML & Visual Analytics Platform for Geriatric Hospital System Mgmt





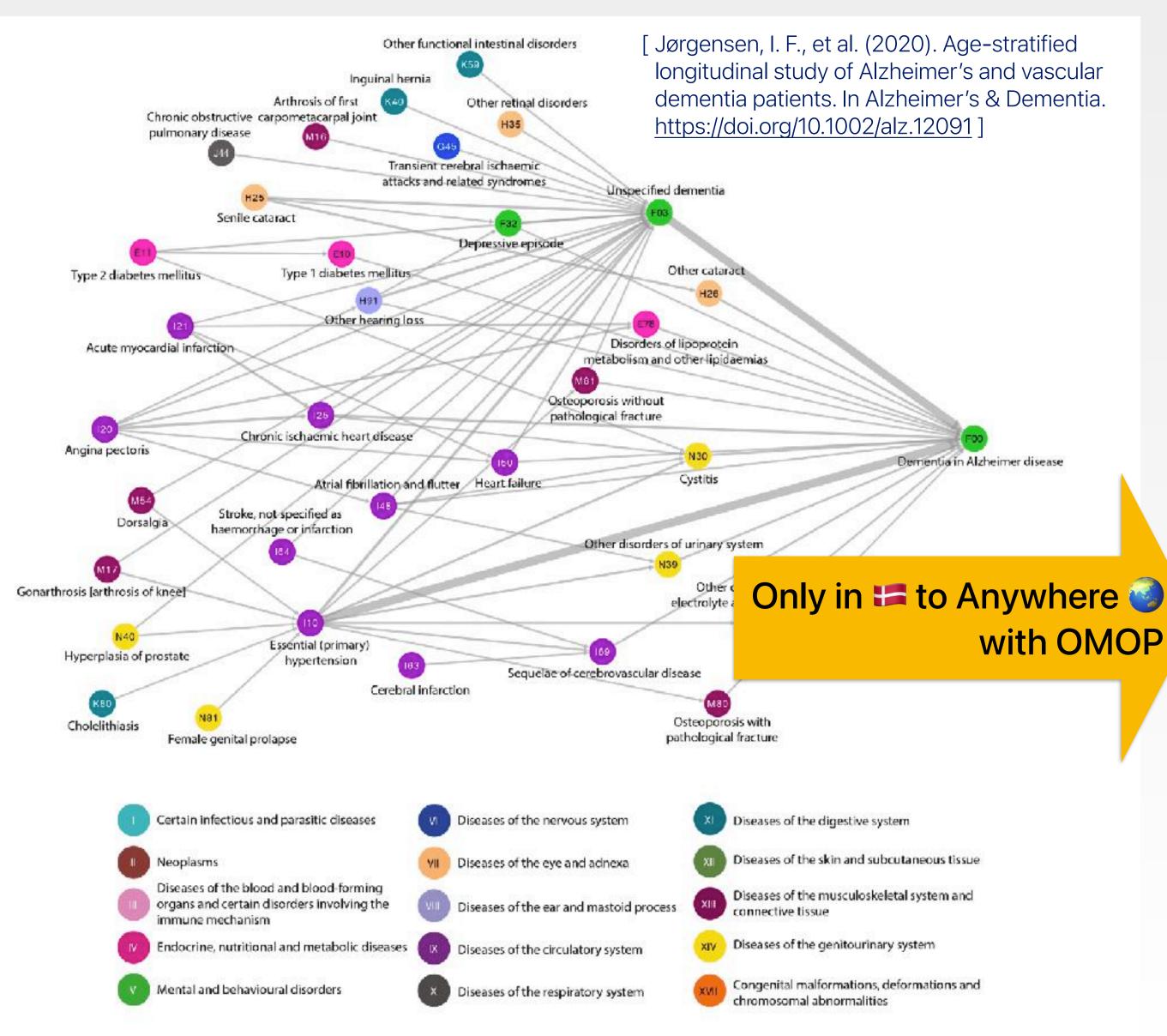
There will be a separate workshop focusing on ETL & conversion.



on OMOP CDM

### Can we make our model more GENERALIZABLE?

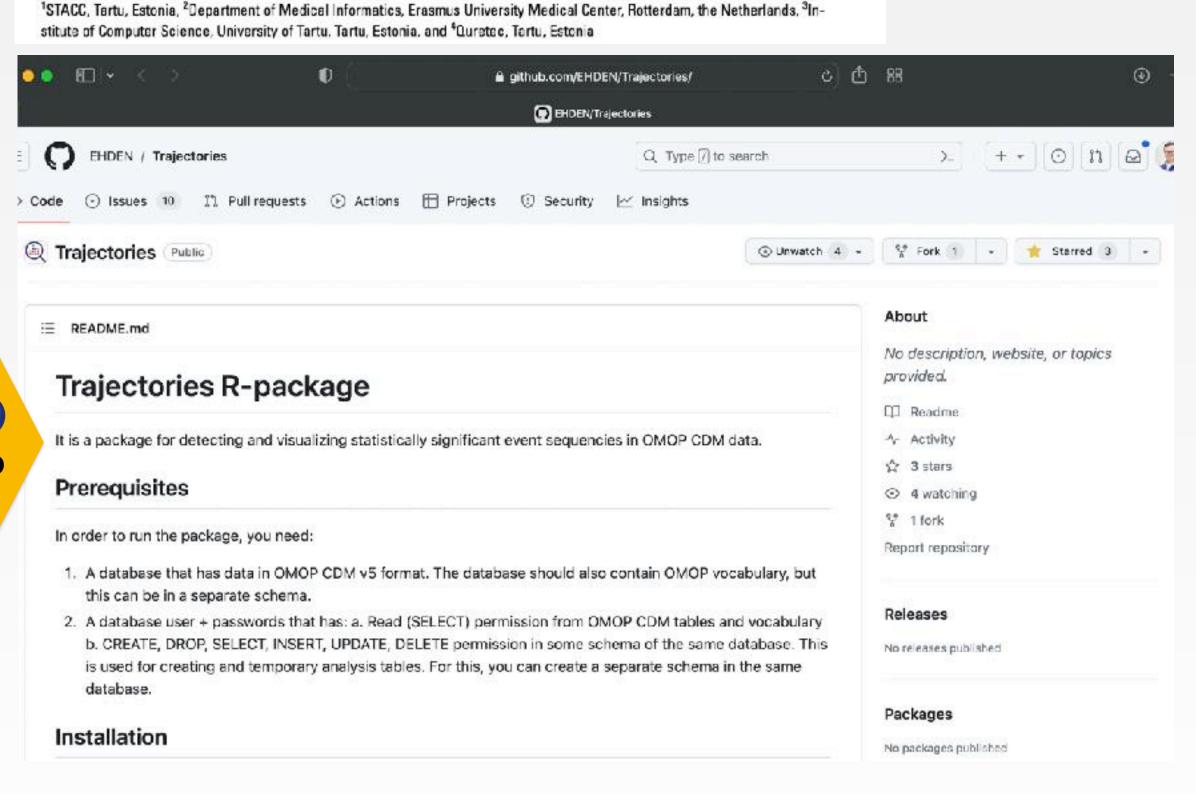




Trajectories: a framework for detecting temporal clinical event sequences from health data standardized to the Observational Medical Outcomes Partnership (OMOP) Common Data Model

Kadri Künnapuu<sup>1</sup>, Solomon Ioannou<sup>2</sup>, Kadri Ligi<sup>1,3</sup>, Raivo Kolde<sup>3</sup>, Sven Laur<sup>1,3</sup>, Jaak Vilo (1)<sup>1,3,4</sup>, Peter R. Rijnbeek<sup>2</sup>, and Sulev Reisberg (1)<sup>1,3,4</sup>,





[Künnapuu, K., et al. (2022). <a href="https://doi.org/10.1093/jamiaopen/ooac021">https://github.com/EHDEN/Trajectories/</a>]



# How can we pool large amount of data for

research in a short period of time?



Dovepress

open access to scientific and medical research

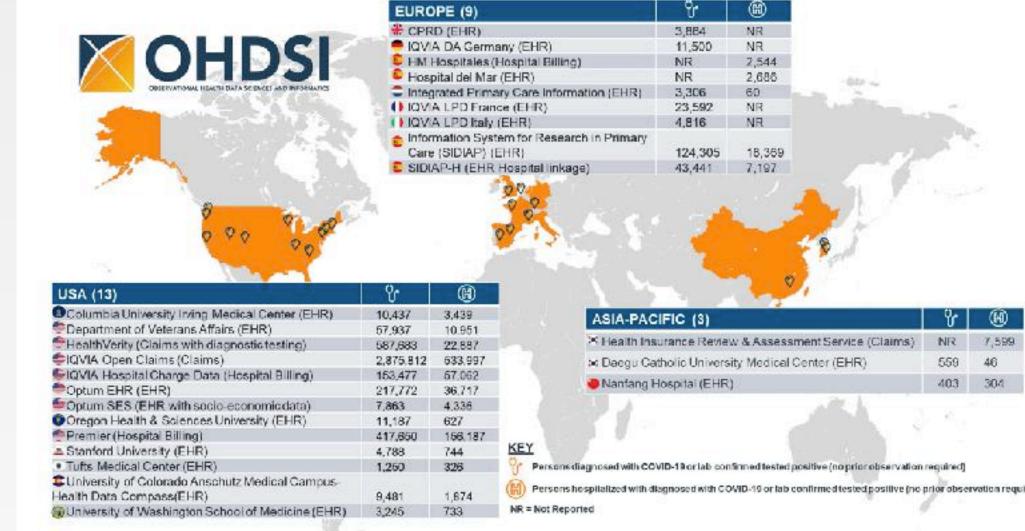
Open Access Full Text Article

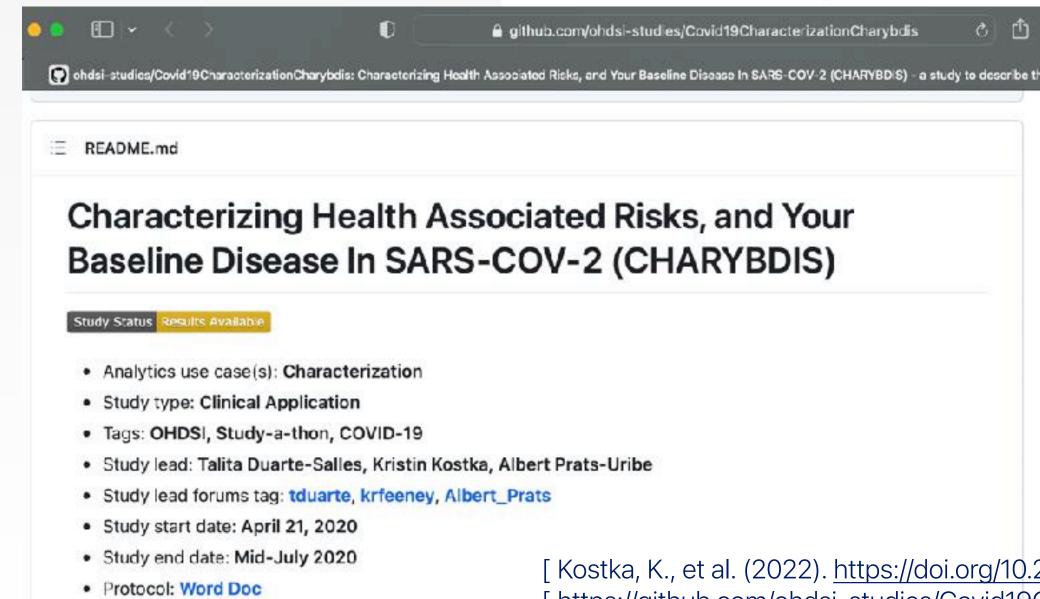
ORIGINAL RESEARCH

### Unraveling COVID-19: A Large-Scale Characterization of 4.5 Million COVID-19 Cases Using CHARYBDIS

Kristin Kostka 1.2, Talita Duarte-Salles 3, Albert Prats-Uribe 4, Anthony G Sena 5,6, Andrea Pistillo 3, Sara Khalid Lana YH Lai 7, Asieh Golozar 8,9, Thamir M Alshammari 10, Dalia M Dawoud 11, Fredrik Nyberg 12, Adam B Wilcox 13,14, Alan Andryc 5, Andrew Williams 15, Anna Ostropolets 16, Carlos Areia 17, Chi Young Jung 18, Christopher A Harle 19, Christian G Reich 12, Clair Blacketer 5,6, Daniel R Morales 20, David A Dorr 21, Edward Burn 3,4, Elena Roel 2,2, Eng Hooi Tan 4, Evan Minty 2, Frank DeFalco 5, Gabriel de Maeztu 4, Gigi Lipori 19, Hiba Alghoul 5, Hong Zhu 6, Jason A Thomas 1, Jiang Bian 19, Jimyung Park 27, Jordi Martínez Roldán 8, Jose D Posada 9, Juan M Banda 3, Juan P Horcajada 11, Julianna Kohler 2, Karishma Shah 3, Karthik Natarajan 16,34, Kristine E Lynch 35,36, Li Liu 3, Lisa M Schilling 8, Martina Recalde 3, Nigam Shah 4, Mengchun Gong Michael E Matheny 40,41, Neus Valveny 4, Nicole G Weiskopf 1, Nigam Shah 2, Osaid Alser 3, Paula Casajust 4, Rae Woong Park 7, Robert Schuff 1, Sarah Seager 1, Scott L DuVall 3, Seng Chan You 5, Seokyoung Song 4, Sergio Fernández-Bertolín 3, Stephen Fortin 5, Tanja Magoc 19, Thomas Falconer 16, Vignesh Subbian 4, Vojtech Huser 4, Waheed-Ul-Rahman Ahmed 3, Patrick B Ryan 5, Marc A Suchard 5, Daniel Prieto-Alhambra 6

<sup>1</sup>IQVIA, Cambridge, MA, USA; <sup>2</sup>OHDSI Center at The Roux Institute, Northeastern University, Portland, ME, USA; <sup>3</sup>Fundació Institut Universitari per a la recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAP/Gol), Barcelona, Spain; \*Centre for Statistics in Medicine, NDORMS, University of Oxford, Oxford, UK; 5 Janssen Research & Development, Titusville, NJ, USA; 6 Department of Medical Informatics, Erasmus University Medical Center, Rotterdam, The Netherlands; 7School of Medical Sciences, University of Manchester, Manchester, UK; 8Regeneron Pharmaceuticals, Tarrytown, NY, USA; Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA; <sup>10</sup>College of Pharmacy, Riyadh Elm University, Riyadh, Saudi Arabia; <sup>11</sup>National Institute for Health and Care Excellence, London, UK; <sup>12</sup>School of Public Health and Community Medicine, Institute of Medicine, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden; <sup>13</sup>Department of Biomedical Informatics and Medical Education, University of Washington, Seattle, WA, USA; <sup>14</sup>Unviersity of Washington Medicine, Seattle, WA, USA; 15 Tufts Institute for Clinical Research and Health Policy Studies, Boston, MA, USA; 16 Department of Biomedical Informatics, Columbia University Irving Medical Center, New York, NY, USA; 17 Nuffield Department of Clinical Neurosciences, University of Oxford, Oxford, UK; 18 Division of Respiratory and Critical Care Medicine, Department of Internal Medicine, Daegu Catholic University Medical Center, Daegu, South Korea; 19 University of Florida Health, Gainesville, FL, USA; 20 Division of Population Health and Genomics, University of Dundee, Dundee, UK; 21 Department of Medical Informatics & Clinical Epidemiology, Oregon Health & Science University, Portland, OR, USA; <sup>22</sup>Universitat Autònoma de Barcelona, Barcelona, Spain; <sup>23</sup>O'Brien Institute for Public Health, Faculty of Medicine, University of Calgary, Calgary, Canada; 24 IOMED, Barcelona, Spain; 25 Faculty of Medicine, Islamic University of Gaza, Gaza, Palestine; 26 Nanfang Hospital, Southern Medical University, Guangzhou, People's Republic of China; 27Department of Biomedical Sciences, Ajou University Graduate School of Medicine, Suwon, South Korea; 28 Director of Innovation and Digital Transformation, Hospital del Mar, Barcelona, Spain; 29 Department of Medicine, School of Medicine, Stanford University, Redwood City, CA, USA; 30 Georgia State University, Department of Computer Science, Atlanta, GA, USA; 31 Department of Infectious Diseases, Hospital del Mar, Institut Hospital del Mar d'Investigació Mèdica (IMIM), Universitat Autònoma de Barcelona, Universitat Pompeu Fabra, Barcelona, Spain; 32United States Agency for International Development, Washington, DC, USA; 33Botnar Research Centre, NDORMS, University of Oxford, Oxford, UK; 34New York-Presbyterian Hospital, New York, NY, USA; 35VA Informatics and Computing Infrastructure, VA Salt Lake City Health Care System, Salt Lake City, UT, USA; 36Department of Internal Medicine, University of Utah School of Medicine, Salt Lake City, UT, USA; 37 Biomedical Big Data Center, Nanfang Hospital, Southern Medical University, Guangzhou, People's Republic of China; 38Data Science to Patient Value Program, School of Medicine, University of Colorado Anschutz Medical Campus, Aurora, CO. USA; 39 Institute of Health Management, Southern Medical University, Guangzhou, People's Republic of China; 40 Tennessee Valley Healthcare System, Veterans Affairs Medical Center, Nashville, TN, USA; 41 Department of Biomedical Informatics, Vanderbilt University Medical Center, Nashville, TN, USA; 42Real-World Evidence, TFS, Barcelona, Spain; 43Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA; <sup>44</sup>Department of Biomedical Informatics, Ajou University School of Medicine, Suwon, South Korea; <sup>45</sup>Department of Preventive Medicine, Yonsei





How can we make EHR data readily

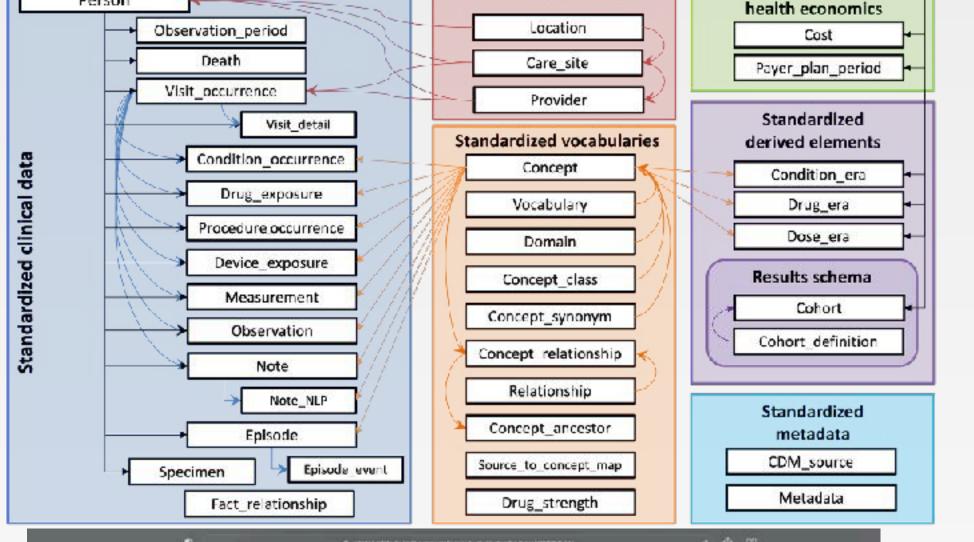
available for research?

Many databases across the hospital

**OMOP CDM standard** 







Standardized health system

Clinical Data Tables OBSERVATION\_PERIOD VISIT\_OCCURRENCE VISIT DETAIL CONDITION OCCURRENCE DRUG\_EXPOSURE ETL Conventions PROCEDURE\_OCCURRENC

DE/ICE\_EXPOSURE MEASUREMEN. OBSERVATION NOTE NIP FACT\_RELATIONSHIP Health System Data Tables

Health Economics Data Tables

Standardized Derived Elements **Metadata Tables** 

Vocabulary Tables

Clinical Data Tables PERSON

This table serves as the central identity management for all Persons in the database, it contains records that uniquely identify each

Mahidol University

Faculty of Medicine Siriraj Hospital

person or patient, and some demographic information.

All records in this table are independent Persons

All Persons in a database needs one record in this table, unless they fall data quality requirements specified in the ETL. Persons with no Events should have a record nonetheless. If more than one data source contributes Events to the database, Persons must be reconciled, if possible, across the sources to create one single record per Person. The content of the BIRTH\_DATETIME must be

DM Rold	User Guide	ETL Conventions	Datztype	Required	Primary Key	Foreign Pey	FK Table	FK Domain
erson_id	It is assumed that every person with a different unique identifier is in fact a different person and should be treated independently.	Any personlinkage that needs to occur touniquely identify Persons cught to be done prior to writing this table. This dentifier can be the criginal id from the source data provided if it is an integer, otherwise it can be an autogenerated number.	integer	Yes	Yes	No		
ender_concept_id	This field is meant to capture the biological sex at birth of the Person. This field should not be used to study gender identity issues.	Use the gender or sex value present in the data under the assumption that it is the biological sex at birth. If the source data captures gender identity it should be stored in the ORSERVATION table.  Accested gender concepts	integer	Yes	No	Yes	CONCEPT	Gerder
ear of hirth		For cuts course with date of		Voc	Min	No.		

birth, the year should be







# Introduction to OMOP CDM and OHDSI





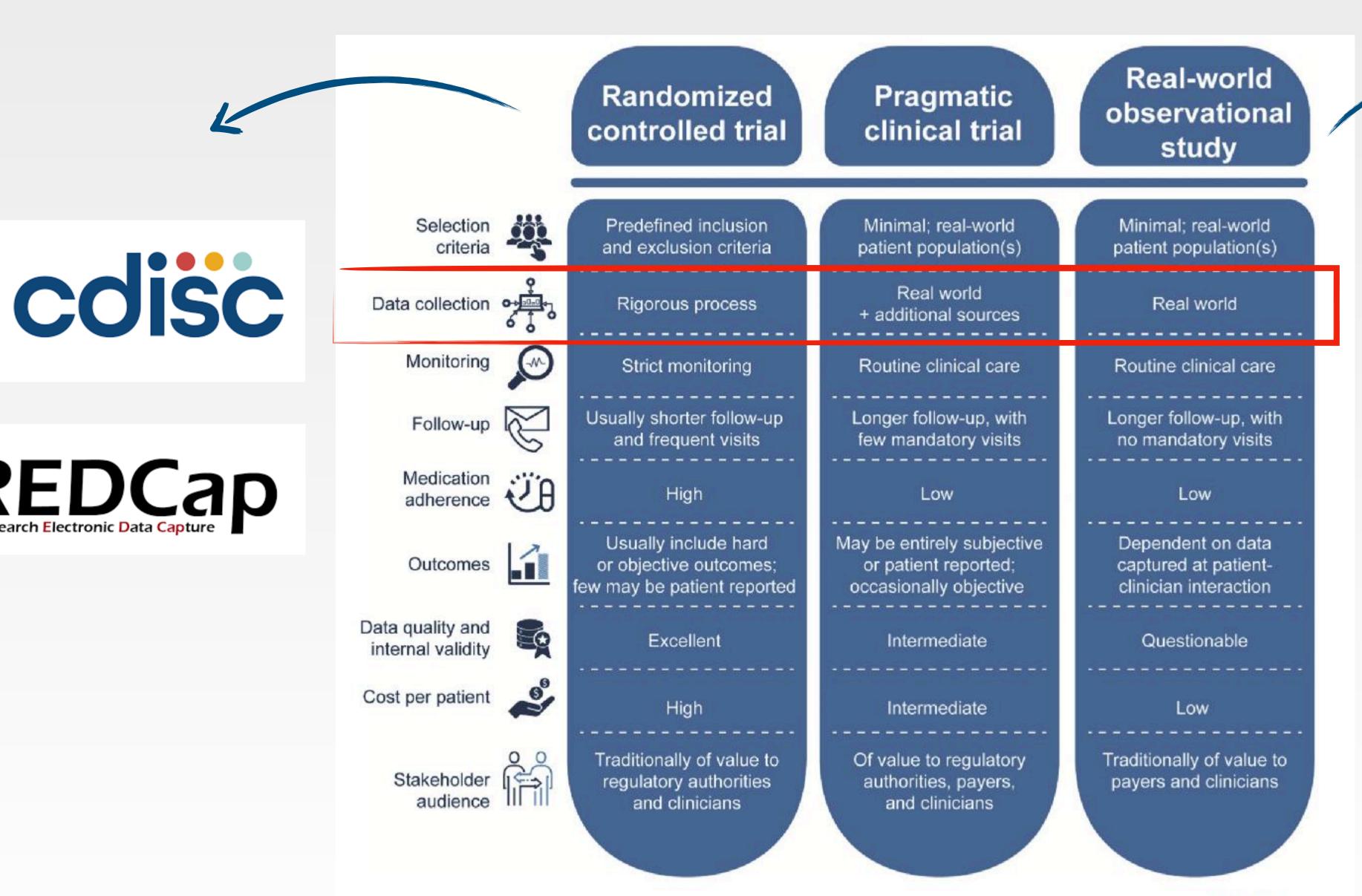




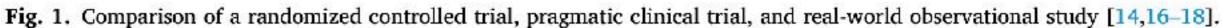
### Session Overview

### Introduction to OMOP CDM and OHDSI @ 09:30 – 10:30 (60 min)

<ul> <li>What are the challenges in healthcare data standardization?</li> <li>What are OMOP CDM and OHDSI? Why do they exist?</li> <li>What are real-world data (RWD) and real-world evidence (RWE)?</li> <li>How can OMOP/OHDSI help my research?</li> <li>Selected contents from The Book of OHDSI chapter 1 – 6         <ul> <li>https://ohdsi.github.io/TheBookOfOhdsi</li> <li>https://www.ohdsi.org</li> </ul> </li> <li>★ Get the big picture of CDM and OHDSI ecos that the big picture of CDM and OHDSI ecos the big picture of CDM and OHDSI ecos that the big picture of CDM and OHDSI ecos the big picture of CDM and O</li></ul>	ystem P CDM ta d



Research Electronic Data Capture





**OBSERVATIONAL M**EDICAL **O**UTCOMES **PARTNERSHIP** est. 2009





For Healthcare Services







Mahidol University Faculty of Medicine Siriraj Hospital

Patient-level data in source system/schema



# LEGEND Hypertension Study 2019



Real-world evidence — pharmacoepidemiology

THE LANCET

Articles

All-cause mortality

Cardiovascular-related mortality

Comprehensive comparative effectiveness and safety of first-line antihypertensive drug classes: a systematic, multinational, large-scale analysis



Marc A Suchard, Martijn J Schuemie, Harlan M Krumholz, Seng Chan You, Ruijun Chen, Nicole Pratt, Christian G Reich, Jon Duke, David Madigan, George Hripcsak, Patrick B Ryan

"The study factors insurance claim data and electronic health records from 4.9 million patients across nine observational databases, making it the most comprehensive one ever on first-line antihypertensives."

"First-Line Thiazide Diuretic Users Experience 15% Fewer Adverse Cardiovascular Outcomes Than ACE Inhibitor Users"

> Currently running LEGEND T2DM study https://github.com/ohdsi-studies/LegendT2dm

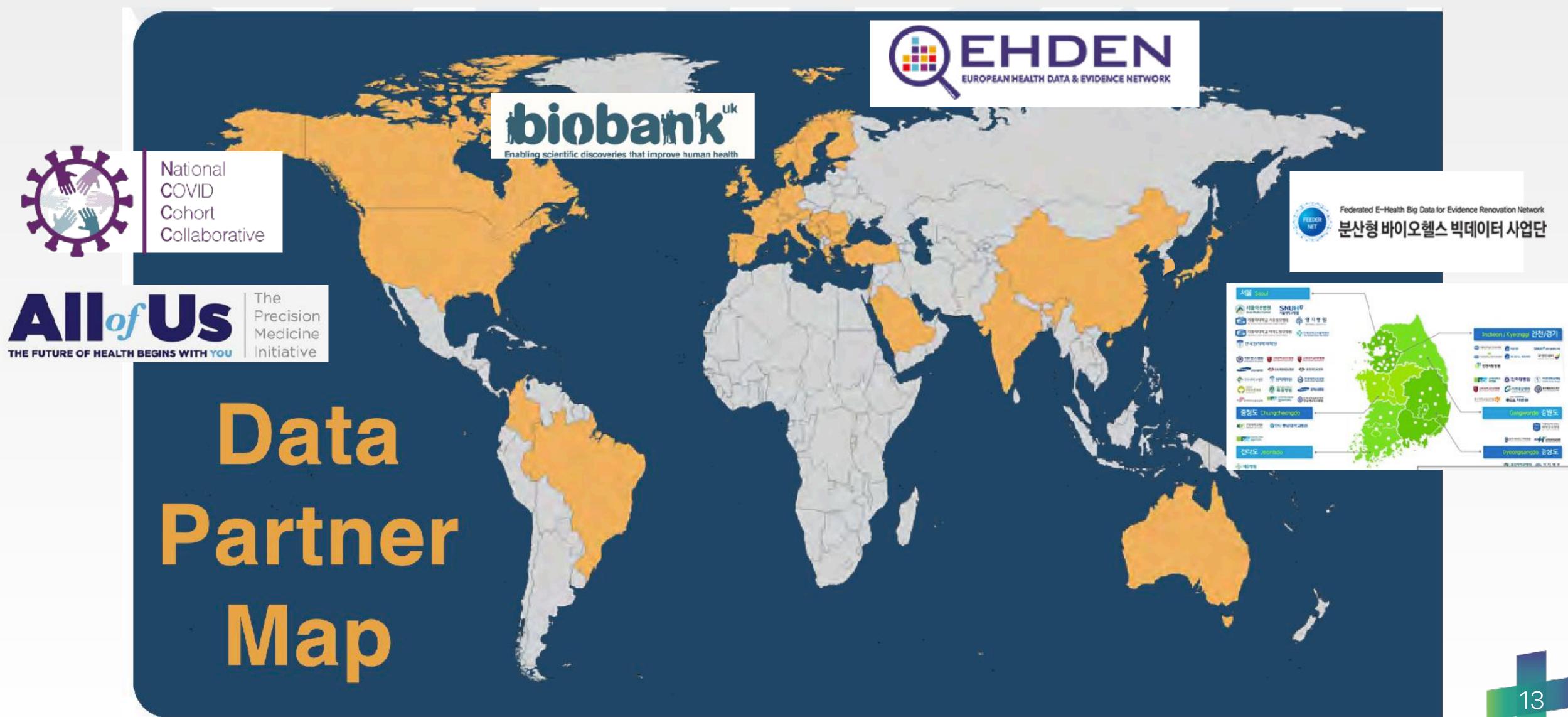
Chest pain or angina Transient ischaemic attack Abnormal weight loss Acute renal failure Chronic kidney disease End stage renal disease Measured renal dysfunction Malignant neoplasm Neutropenia or agranulocytosis Thrombocytopenia Anaphylactoid reaction Venous thromboembolic events Favours THZ Favours ACEi Favours THZ Favours ARE Favours THZ Favours dCCE Favours THZ Favours ndCCB

Figure 2: Meta-analytic safety profiles comparing THZ to ACEi, ARB, dCCB, and ndCCB new users across 46 outcomes listed on product labels Points and lines identify HR estimates with their 95% CIs, respectively. Outcomes in grey signify that the CI covers HR of 1 (null hypothesis of no differential risk). THZ=thiazide or thiazide-like diuretics. ACEi=angiotensin converting-enzyme inhibitors. ARB=angiotensin receptor blockers. dCCB=dihydropyridine calcium channel blockers. ndCCB=non-dihydropyridine calcium channel blockers. HR=hazard ratio.

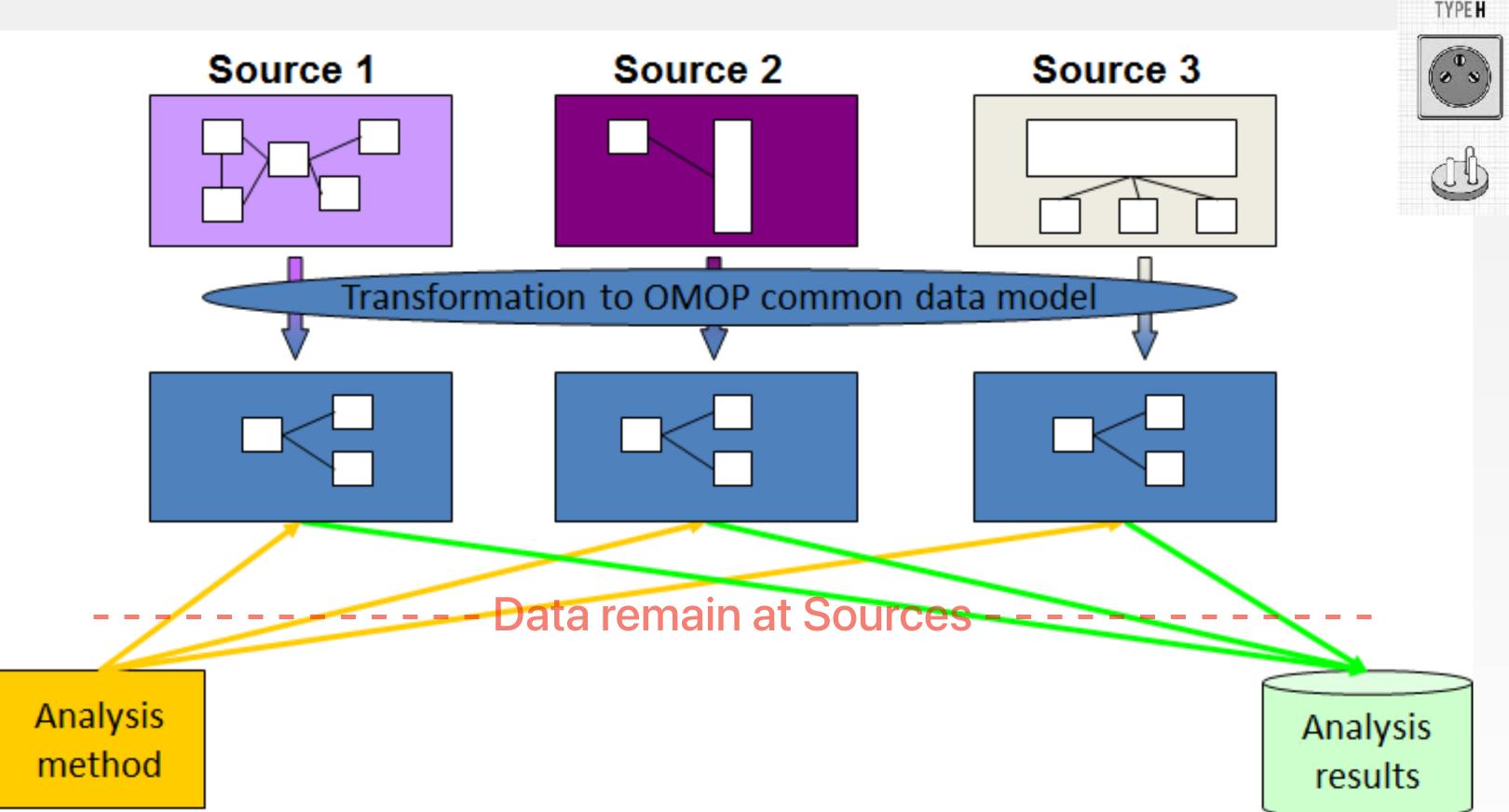




### OMOP CDM Data Partners



### OMOP CDM







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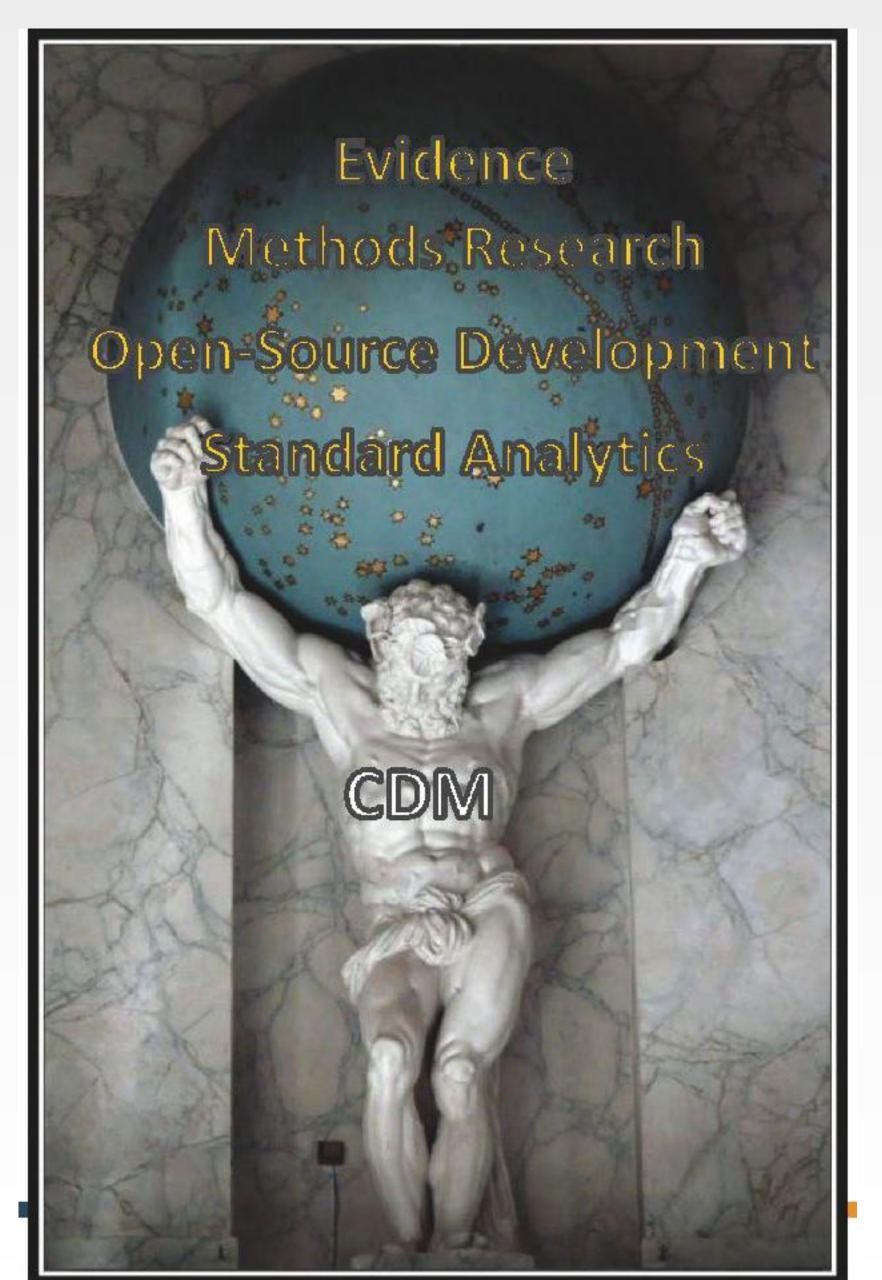




### OMOP CDM

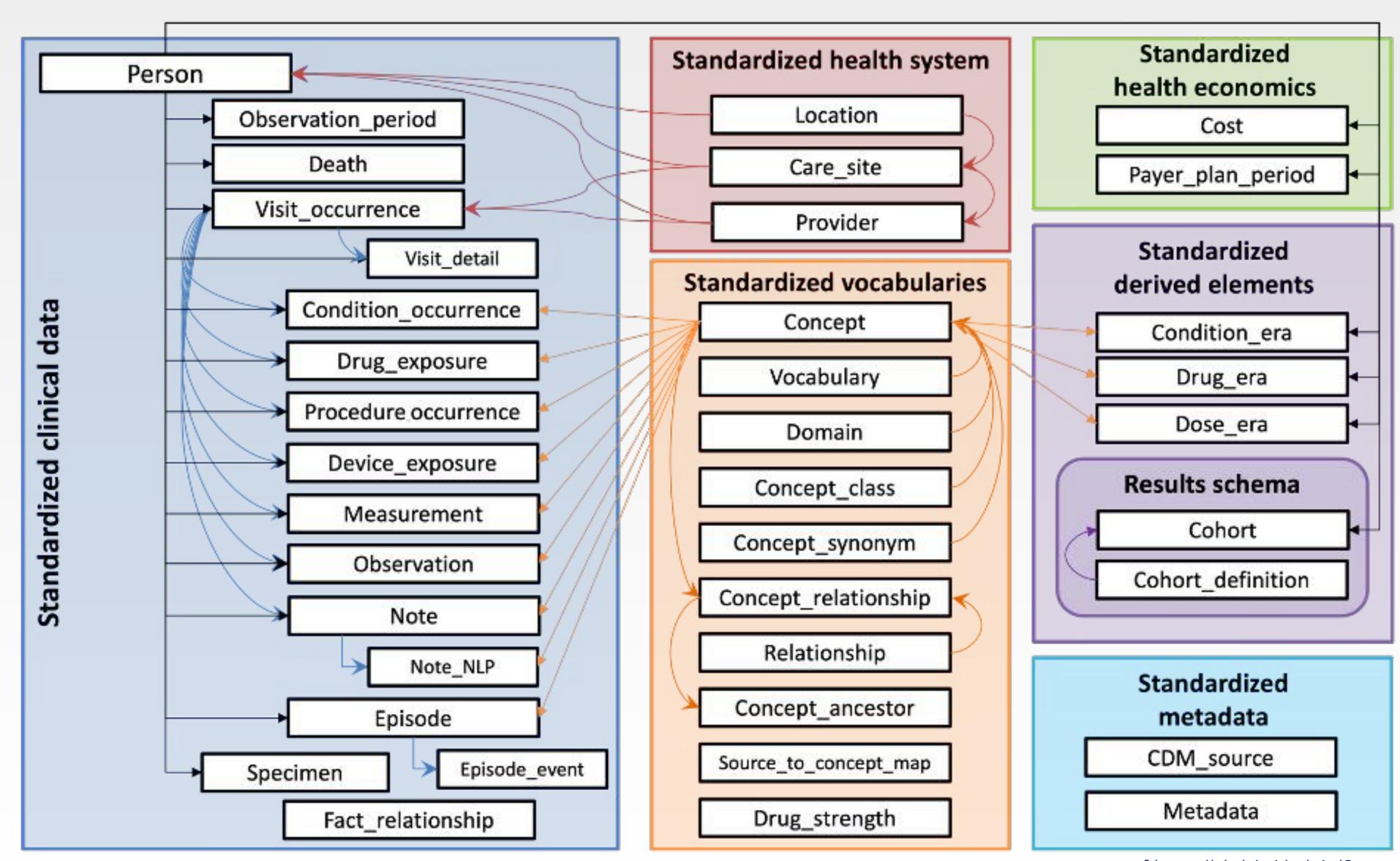
The OMOP CDM is a system of tables, vocabularies, and conventions that allow observational health data to be standardized.

It is this standard approach that facilitates rapid innovation in the areas of open-source development, methods research, and evidence generation.





### OMOP CDM: Tables





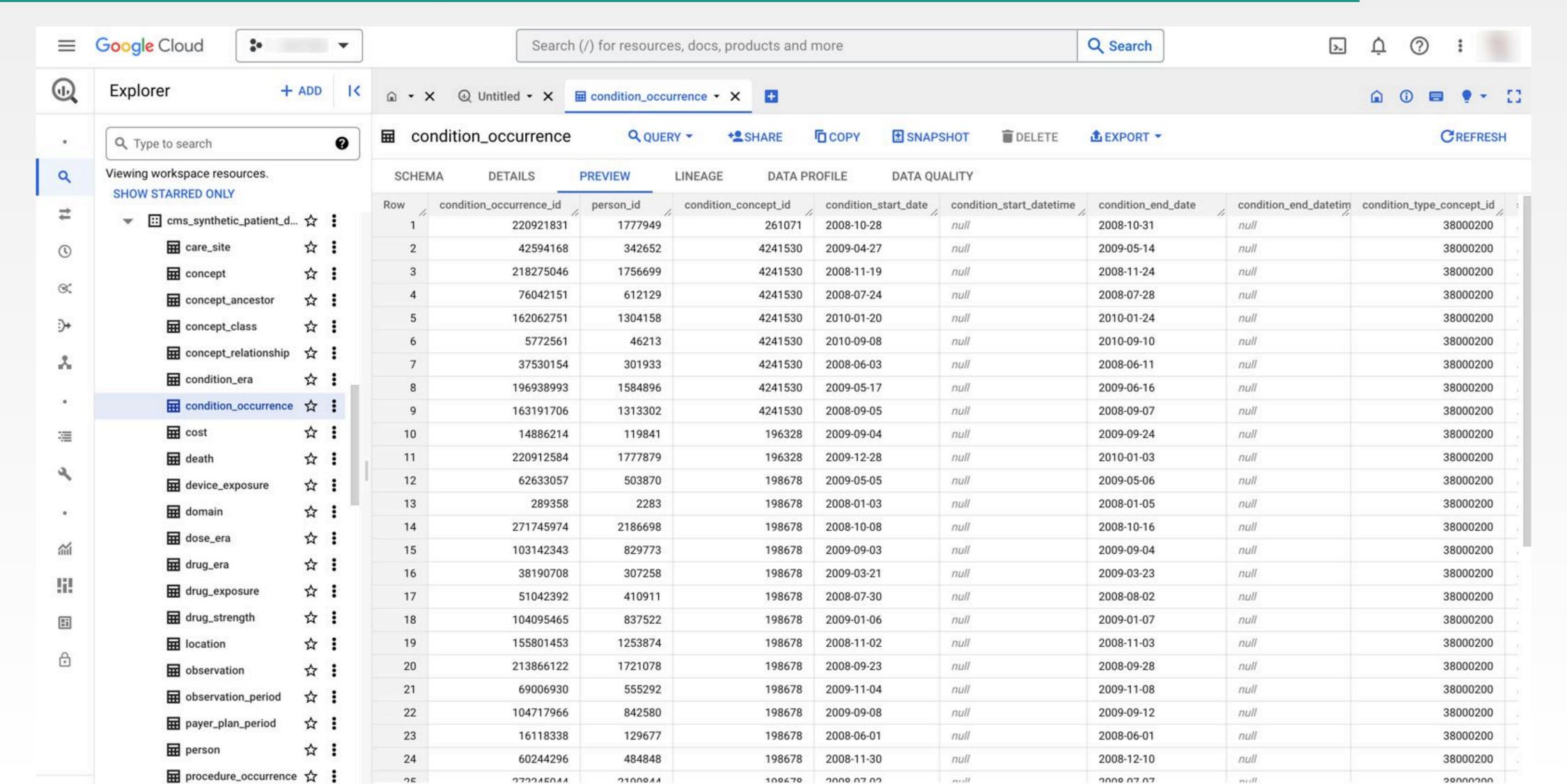
# OMOP CDM: Table Groups

- 1. **Clinical data** ข้อมูลทางคลินิก มี 17 ตาราง (table) อาทิ Person (ข้อมูลบุคคล) Observation\_period (ระยะเวลาที่เข้า รับบริการ) Visit\_occurrence (การเข้ารับบริการ) Visit\_detail (รายละเอียดการเข้ารับบริการ) Condition\_occurrence (ผลการวินิจฉัยและอาการของโรค) Drug\_exposure (ยาที่ได้รับ) Procedure\_occurrence (หัตถการ) Device\_exposure (อุปกรณ์ทางการแพทย์) Measurement (ผลการตรวจทางห้องปฏิบัติการและกายภาพ) Observation (ผลการตรวจอื่น ๆ) Death (การเสียชีวิต) Note (บันทึกข้อมูลผู้ป่วย) Specimen (สิ่งส่งตรวจ)
- 2. **Vocabularies** คลังคำศัพท์ต้นทาง และ คลังคำศัพท์มาตรฐาน เช่น SNOMED-CT, LOINC, RxNORM เป็นต้น สำหรับ การใช้ข้อมูลร่วมกันระดับนานาชาติ
- 3. Health system ข้อมูลเกี่ยวกับสถานพยาบาล
- 4. Health economics ข้อมูลเกี่ยวกับค่า ใช้จ่าย ในการบริการ
- 5. **Derived elements** ข้อมูลที่สรุปรวมเพิ่มเติม เช่น ระยะเวลาที่เป็นโรค ระยะเวลาที่ได้รับยา การแบ่งกลุ่มผู้ป่วย (cohort)
- 6. Metadata ข้อมูลประกอบ CDM เพิ่มเติม เช่น ที่มา เวอร์ชัน วันที่ปรับปรุง



### OMOP CDM Example data

https://console.cloud.google.com/marketplace/product/hhs/synpuf





### Who created and maintain OMOP?

2009: **Observational Medical Outcomes Partnership (OMOP)** was a public-private partnership, chaired by the US Food and Drug Administration, administered by the Foundation for the National Institutes of Health, and funded by a consortium of pharmaceutical companies that collaborated with academic researchers and health data partners to establish a research program that sought to advance the science of active medical product safety surveillance using observational healthcare data.



since 2014: Observational Health Data Sciences and Informatics (OHDSI) is an open-science community that aims to improve health by empowering the community to collaboratively generate the evidence that promotes better health decisions and better care.



### OHDSI's Vision

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

through these objectives:

Innovation, Reproducibility, Community, Collaboration, Openness, Beneficence





# OHDSI Workgroup

as of 2022

#### APAC (Asia-Pacific)

Current Participants: 289 Lead: Mui Van Zandt

#### **Common Data Model**

Current Participants: 596 Lead: Clair Blacketer

#### Education

Current Participants: 116 Lead: Nigel Hughes

### Geographic Information System (GIS)

Current Participants: 122 Leads: Robert Miller, Andrew Williams

#### Healthcare Systems

Current Participants: 430 Lead: Melanie Philofsky

#### ATLAS/WebAPI

Current Participants: 226 Lead: Anthony Sena

### Data Quality Dashboard Development

Current Participants: 260 Lead: Clair Blacketer

#### Eye Care & Vision Research

Current Participants: 40 Leads: Sally Baxter, Kerry Goetz

#### HADES (Health Analytics Data-to-Evidence Suite)

Current Participants: 262 Lead: Martijn Schuemie

#### Latin America

Current Participants: 48 Lead: Jose Posada

#### **Clinical Trials**

Current Participants: 252 Leads: Mike Hamidi, Lin Zhen

#### Early-Stage Researchers

Current Participants: 214 Leads: Faaizah Arshad, Ross Williams

#### **FHIR and OMOP**

Current Participants: 214
Leads: Jon Duke, Christian Reich,
Dana Stephenson

#### **Health Equity**

Current Participants: 201 Lead: Jake Gillberg

#### **Medical Devices**

Current Participants: 130 Leads: Vojtech Huser, Asiyah Lin

#### **Medical Imaging**

Current Participants: 114 Leads: Paul Nagy, Seng Chan You

#### Open-Source Community

Current Participants: 118 Leads: Adam Black, Paul Nagy

#### Population-Level Effect Estimation

Current Participants: 355 Leads: Martijn Schuemie, Marc Suchard

#### Steering Group

Current Participants: 70 Lead: Patrick Ryan

#### Natural Language Processing

Current Participants: 379 Lead: Hua Xa

#### Patient-Level Prediction

Current Participants: 355 Leads: Jenna Reps, Ross Williams

#### **Psychiatry**

Current Participants: 115 Leads: Dmitry Dymshyts, Andrew Williams

### Surgery and Perioperative Medicine

Current Participants: 37 Lead: Evan Minty

#### Oncology

Current Participants: 241 Lead: Asieh Golozar

### Phenotype Development & Evaluation

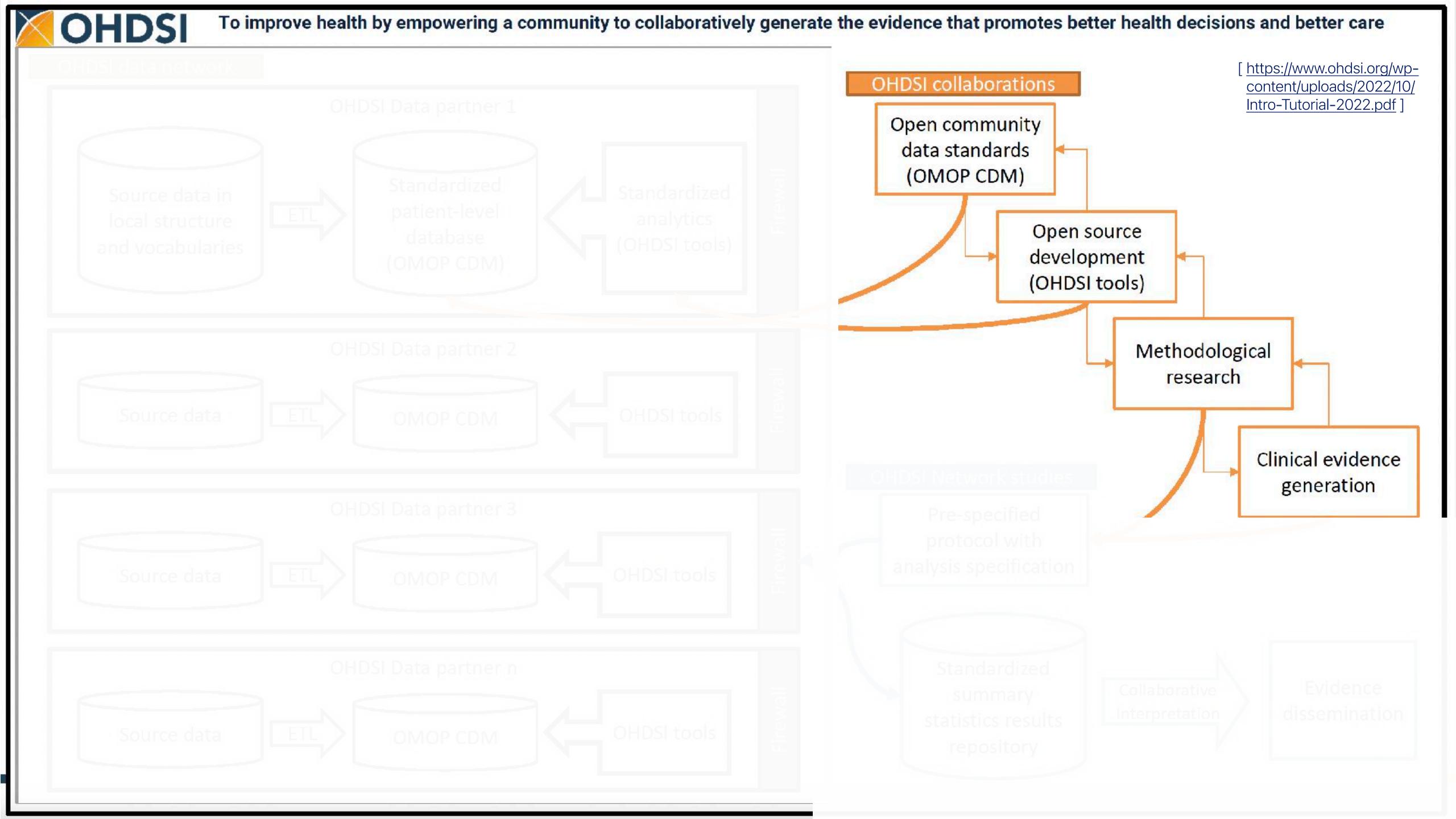
Current Participants: 249 Lead: Gowtham Rao

#### Registry

Current Participants: 115 Lead: Tina Parciak

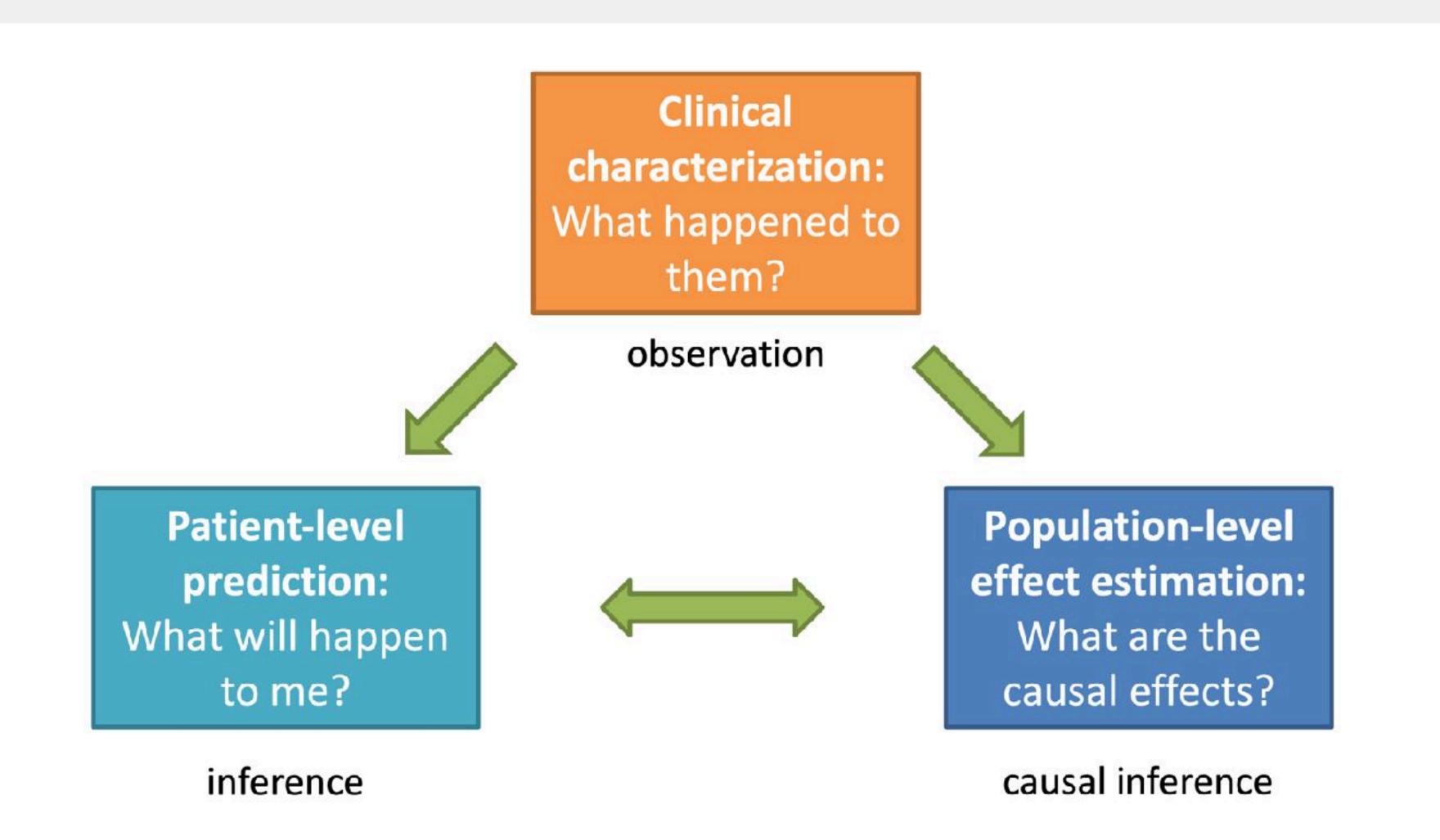
#### **Vaccine Vocabulary**

Current Participants: 76 Lead: Adam Black

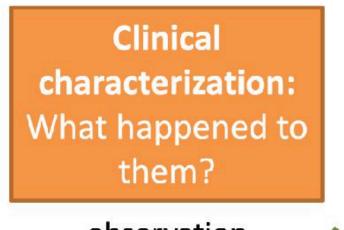




## Main Analytics/Research Use Cases



### Characterization





observation

Typical Questions	Desired output
<ul> <li>How many patients?</li> <li>How often does?</li> <li>What proportion of patients?</li> <li>What is the distribution of values for lab?</li> <li>What are the HbA1c levels for patients with?</li> <li>What are the lab values for patients?</li> <li>What is the median length of exposure for patients on?</li> <li>What are the trends over time in?</li> <li>What are other drugs that these patients are using?</li> <li>What are concomitant therapies?</li> <li>Do we have enough cases of?</li> <li>Would it be feasible to study X?</li> </ul>	<ul> <li>Count or percentage</li> <li>Averages</li> <li>Descriptive statistics</li> <li>Incidence rate</li> <li>Prevalence</li> <li>Cohort</li> <li>Rule-based phenotype</li> <li>Drug utilization</li> <li>Disease natural history</li> <li>Adherence</li> <li>Co-morbidity profile</li> <li>Treatment pathways</li> </ul>
<ul> <li>What are the demographics of?</li> <li>What are the risk factors of? (if identifying a specific risk factor, maybe estimation, not prediction)</li> <li>What are the predictors of?</li> </ul>	Line of therapy

### Population-Level Estimation

Population-level effect estimation:
What are the causal effects?





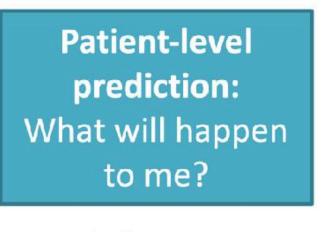
causal inference

Typical Questions	Desired output
<ul> <li>What is the effect of?</li> <li>What if I do intervention?</li> <li>Which treatment works better?</li> <li>What is the risk of X on Y?</li> <li>What is the time-to-event of?</li> </ul>	<ul> <li>Relative risk</li> <li>Hazards ratio</li> <li>Odds ratio</li> <li>Average treatment effect</li> <li>Causal effect</li> <li>Association</li> <li>Correlation</li> <li>Safety surveillance</li> <li>Comparative effectiveness</li> </ul>

### The data can provide answers to questions like:

- For patients newly diagnosed with atrial fibrillation, in the first year after therapy initiation, does warfarin cause more major bleeds than dabigatran?
- Does the causal effect of metformin on diarrhea vary by age?

### Characterization





inference

Typical Questions	Desired output
<ul> <li>What is the chance that this patient will?</li> <li>Who are candidates for?</li> </ul>	<ul> <li>Probability for an individual</li> <li>Prediction model</li> <li>High/low risk groups</li> <li>Probabilistic phenotype</li> </ul>

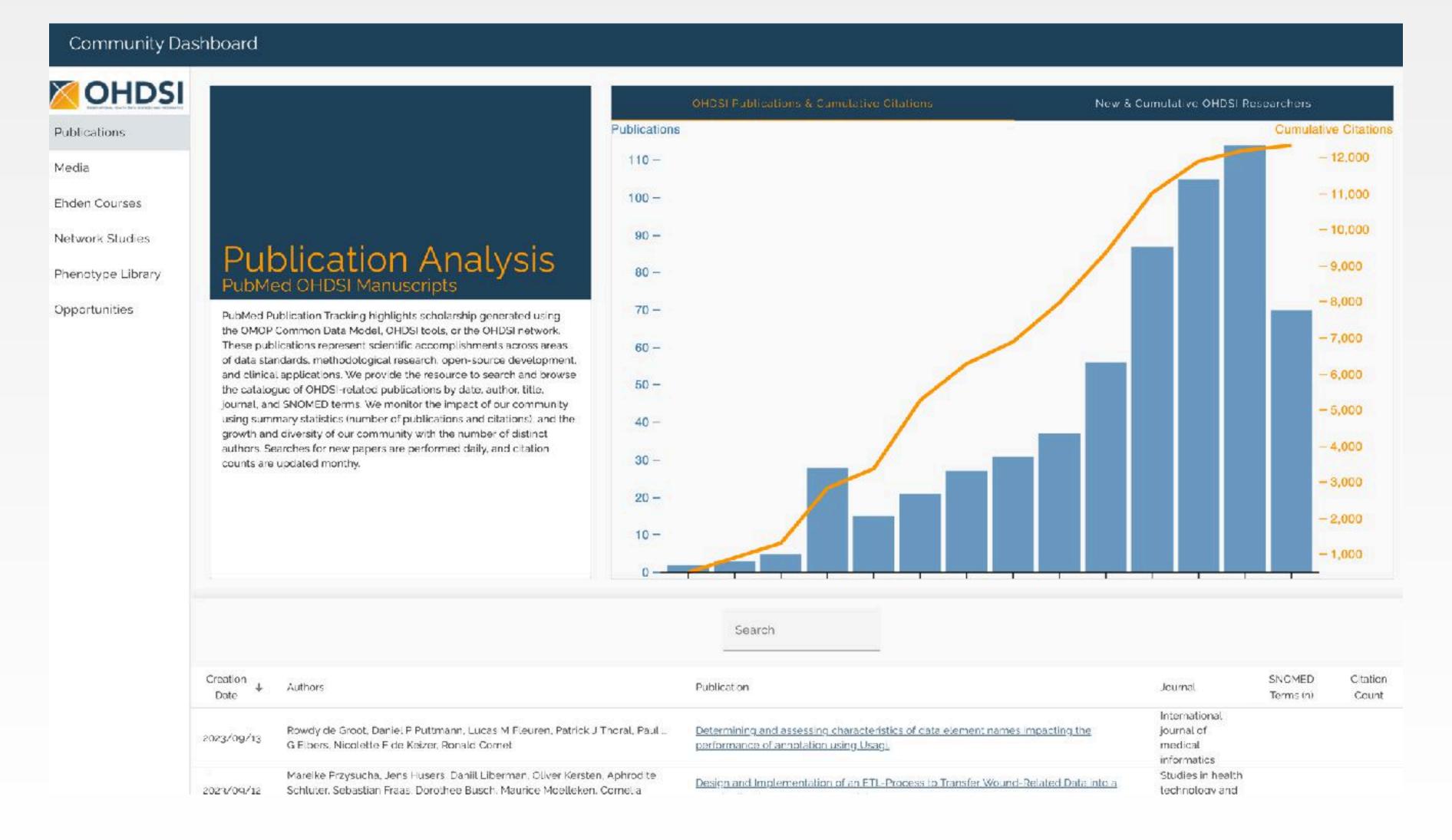
### The data can provide answers to questions like:

- For a specific patient newly diagnosed with major depressive disorder, what is the probability the patient will attempt suicide in the first year following diagnosis?
- For a specific patient newly diagnosed with atrial fibrillation, in the first year after therapy initiation with warfarin, what is the probability the patient suffers an ischemic stroke?



## Catalog: Published Studies

https://dash.ohdsi.org/pubmed







# Catalog: Past & Ongoing Studies

https://data.ohdsi.org/OhdsiStudies/



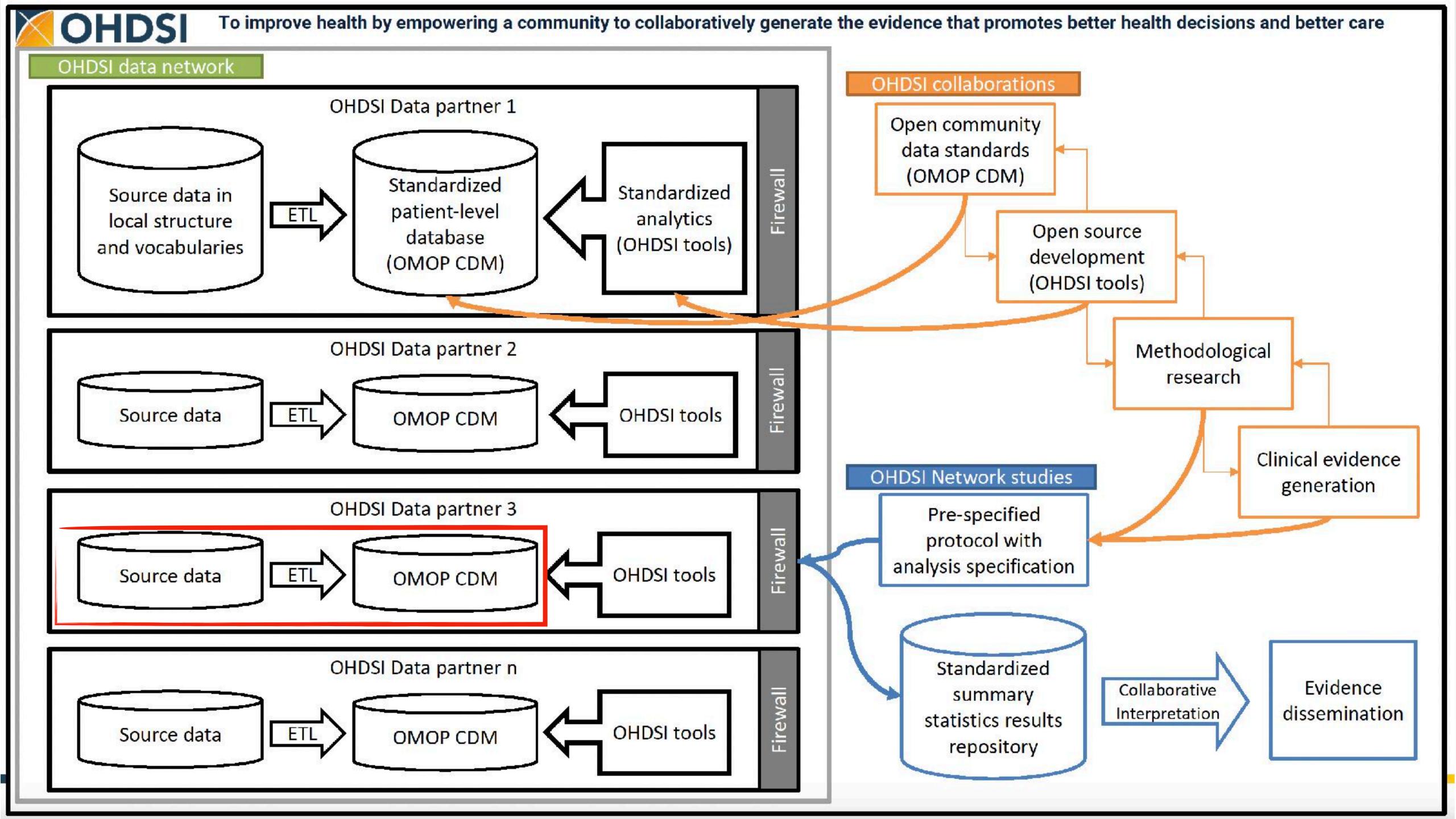
### **OHDSI Studies**

OHDSI is a global, open-science community that is committed to generating real-world evidence to both support clinical decision-making and advance the methodology within this field. We have collaborated on many network studies across our community, many of which (both past and ongoing) are listed in this table. Please click on any listing that interests you to learn more about the study, and how you can potentially collaborate to generate reliable, reproducible evidence.

show 15 \$ entries					Search:		
Title	Use cases	Study type	Tags	Status	Lead(s)	Start date	Last change
All	All	All	All	All	All	All	All
Deep Learning Comparison	Patient-Level Prediction	Methods Research	Deep Learning	Repo Created		(a) ) in	2023-09-12
arge-scale Evidence Generation and Evaluation acr	Population-Level Estimation	Clinical Application		Results Available	Marc A. Suchard		2023-09-11
Small-Sample Comparative-Effect Estimation Evaluat	Population-Level Estimation	Methods Research		Started	Martijn Schuemie	2020-12-03	2023-09-11
Phenotype Library Diagnostics	Characterization	Clinical Application		Results Available	Gowtham Rao	2020-10-08	2023-08-31
ovid-19 vaccine adverse events of special interes	Characterization	Methods Research	Phenotype error correction, In	Repo Created	James Weaver		2023-08-21
corporating Measurement Values into Patient-Leve	Patient-Level Prediction	Methods Research	Bayesian Inference, Missing Im	Repo Created			2023-08-11
evelopment and evaluation of an algorithm to link	Characterization	Methods Research	Maternal and infant health	Results Available	James Weaver		2023-07-25
fluoroquinolone use associated with the develop				Repo Created	Jack Janetzki, Nicole Pratt, S		2023-07-12
ealth Equity Research Assessment (HERA) Character	Characterization	Clinical Application	OHDSI, Health Equity	Started	Noemie Elhadad		2023-07-06
lisk of kidney failure associated with intravitrea		Population-level estimation		Repo Created	Cindy X. Cai		2023-06-08
elative Risk of Cervical Neoplasms Associated wit	Characterization and Populatio	Clinical Application	iud	Design Finalized	Matthew Spotnitz and Karthik N	. 2019-09-23	2023-05-24
Quantitative bias analysis for outcome phenotype e	Population-Level Estimation	Methods Research	QBA	Results Available	James Weaver		2023-05-18
IgImmCovid	Patient-Level Prediction	Clinical Application	COVID-19	Started	Jiayi Tong, Yong Chen, Jenna R		2023-05-17
GEM (Decentralized Algorithm for Generalized Line	Patient-Level Prediction	Clinical Application	COVID-19	Design Finalized	Jiayi Tong, Yong Chen, Jenna R	5	2023-05-02
dverse Events of Special Interest within COVID-19	Characterization	Clinical Application	COVID-19	Complete	Erica A Voss	2021-11-02	2023-04-18

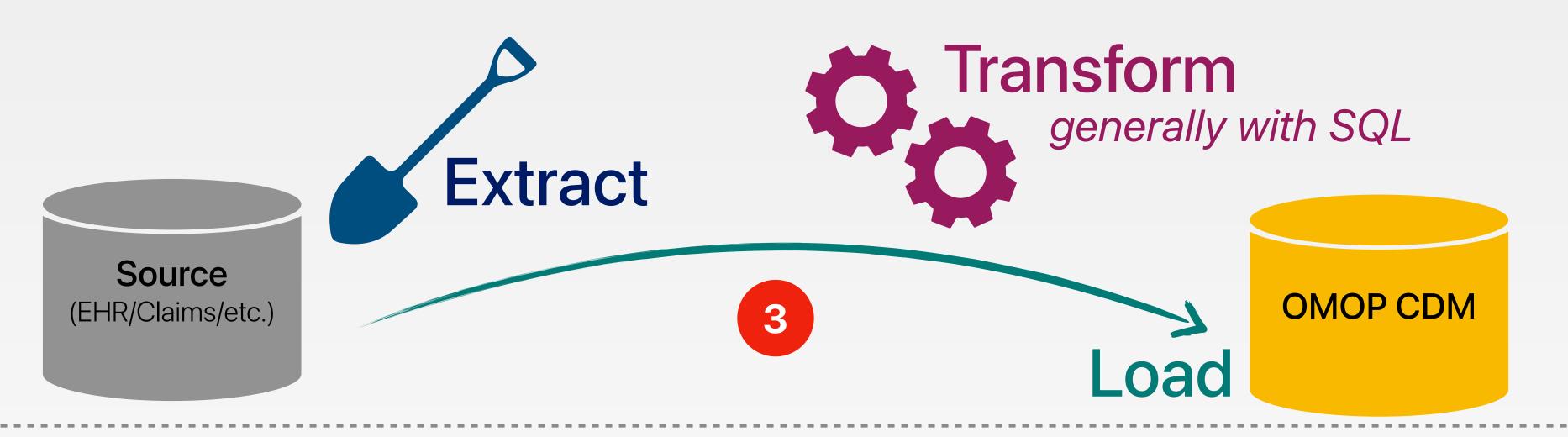
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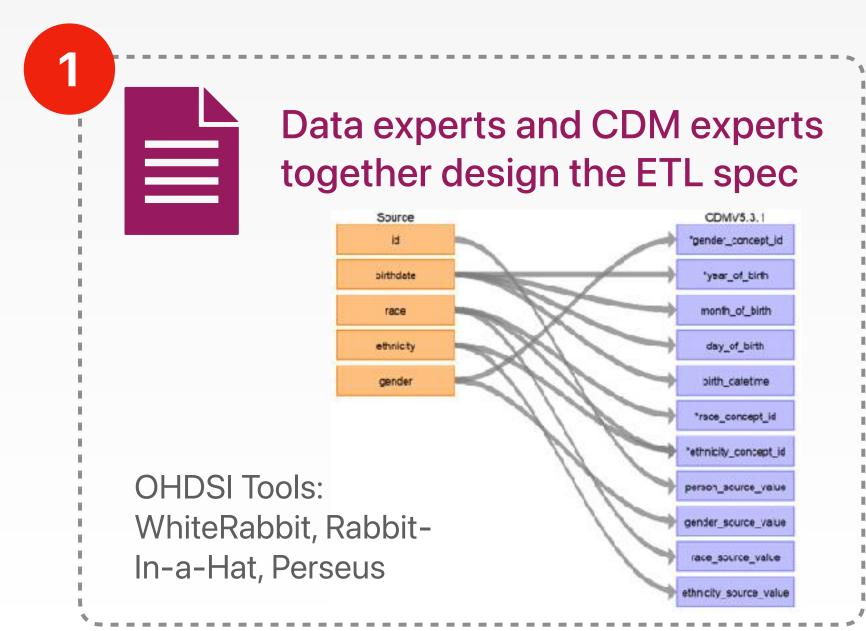
Select a study to see details

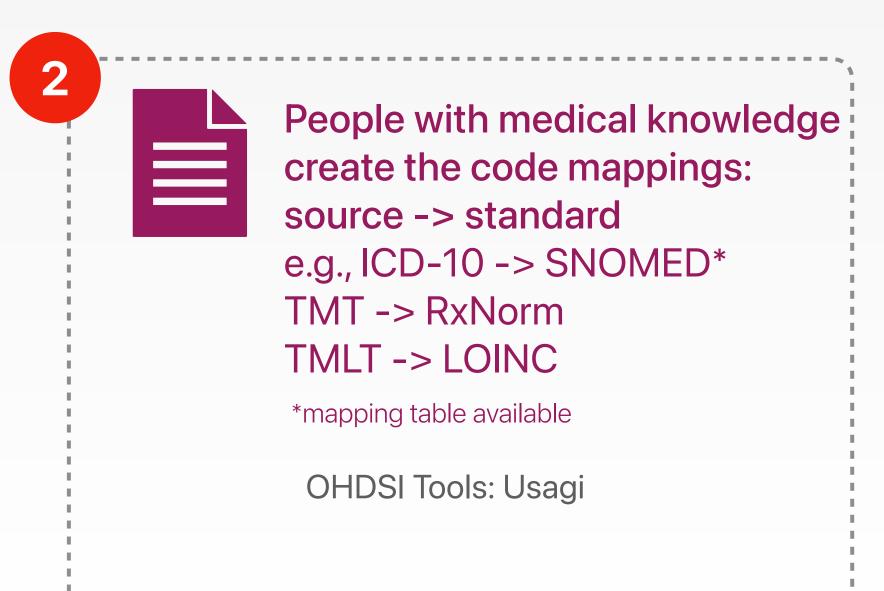


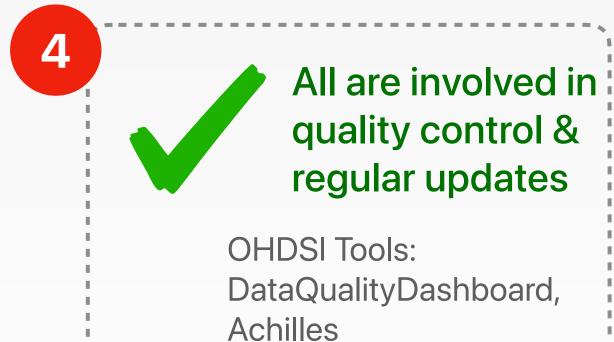


# Extract Transform Load (ETL)









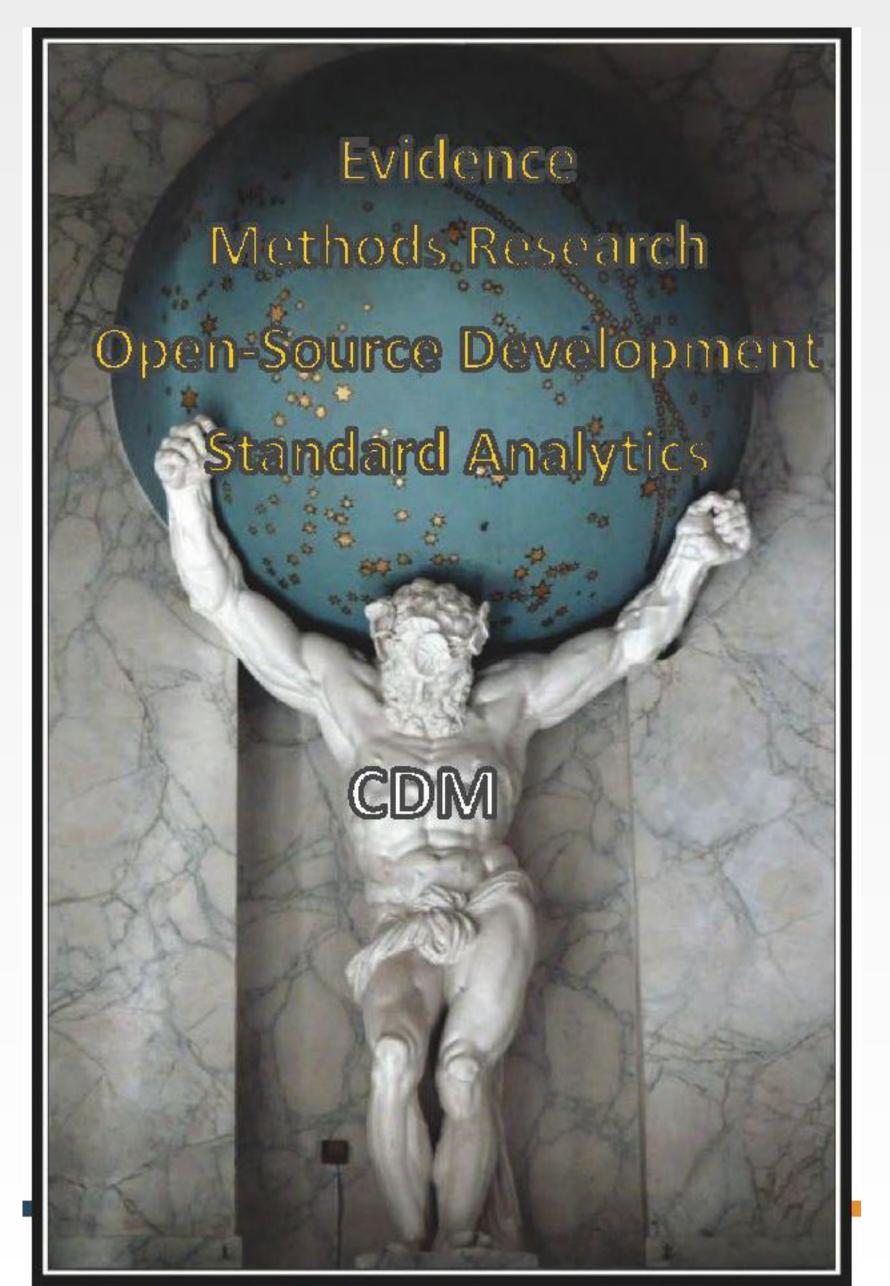




### OMOP CDM

The OMOP CDM is a system of tables, vocabularies, and conventions that allow observational health data to be standardized.

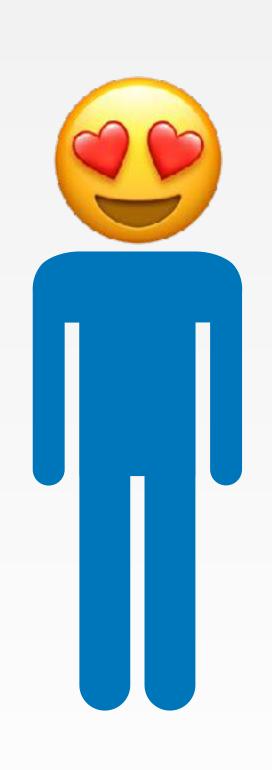
It is this standard approach that facilitates rapid innovation in the areas of open-source development, methods research, and evidence generation.

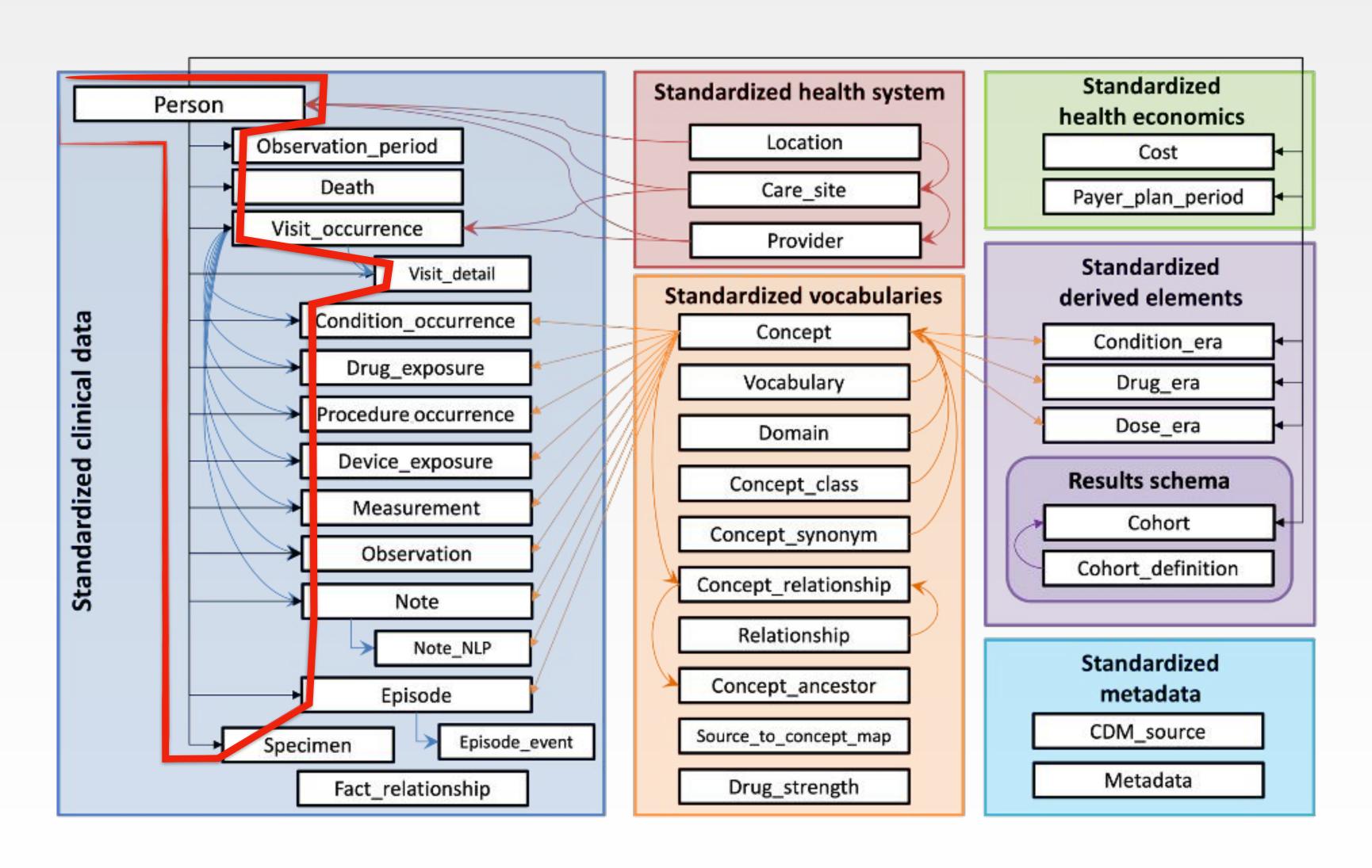




### General Conventions

### The OMOP CDM is a Person centric model







### General Conventions

- Required tables: person and observation\_period
- Common fields:
  - [condition/procedure/drug\_exposure/measurement]\_id รหัส transaction ของแต่ละ ตาราง เป็น primary key
  - [...]\_type\_concept\_id ประเภทที่มาข้อมูลเช่น EHR/Claims, IPD/OPD, Lab, Registry, Survey
  - [...]\_source\_value รหัสโรค/หัตถการ/ยา/แลป/อื่น ๆ ต้นทาง
  - [...]\_source\_concept\_id รหัสโรค/หัตถการ/ยา/แลป/อื่น ๆ ต้นทาง ที่ mapped เป็น ID ของ OMOP
  - [...]\_concept\_id รหัสโรค/หัตถการ/ยา/แลป/อื่น ๆ standard ที่ mapped เป็น ID ของ OMOP

condition_source_value	condition_source_concept_id	condition_concept_id	Standard Code
I10 (ICD10 for Essential (primary) Hypertension)	45591453	320128	59621000 (SNOMED for Essential hypertension)



## Table/Field Conventions

https://ohdsi.github.io/CommonDataModel/cdm54.html

#### **Clinical Data Tables**

#### PERSON

#### **Table Description**

This table serves as the central identity management for all Persons in the database. It contains records that uniquely identify each person or patient, and some demographic information.

#### **User Guide**

All records in this table are independent Persons.

#### **ETL Conventions**

All Persons in a database needs one record in this table, unless they fail data quality requirements specified in the ETL. Persons with no Events should have a record nonetheless. If more than one data source contributes Events to the database, Persons must be reconciled, if possible, across the sources to create one single record per Person. The content of the BIRTH\_DATETIME must be equivalent to the content of BIRTH\_DAY, BIRTH\_MONTH and BIRTH\_YEAR.

Primary Foreign

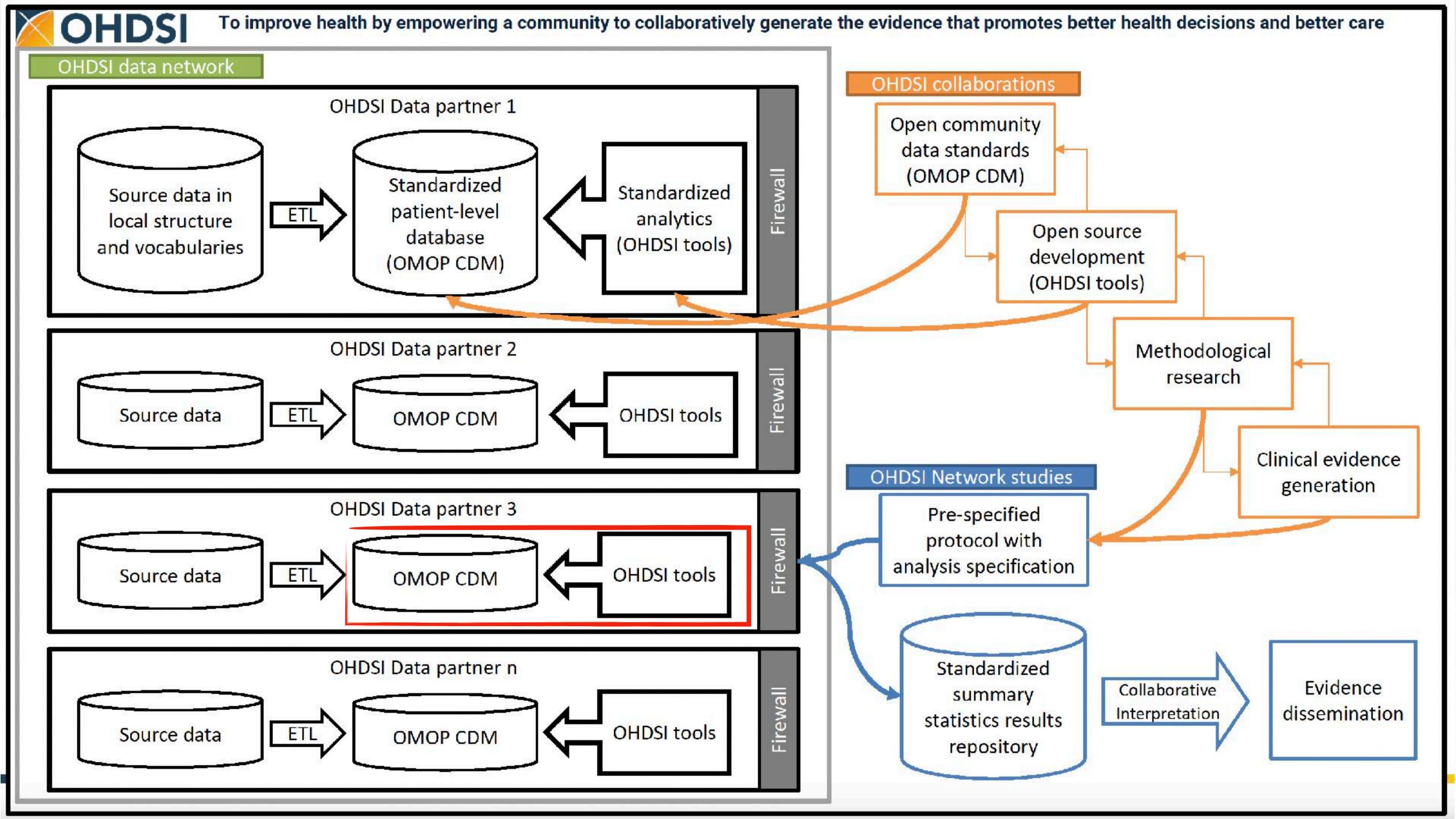
FK

แต่ละ Field มีหลักการ เติมข้อมูลอย่างไร

Table Domain
NCEPT Gender



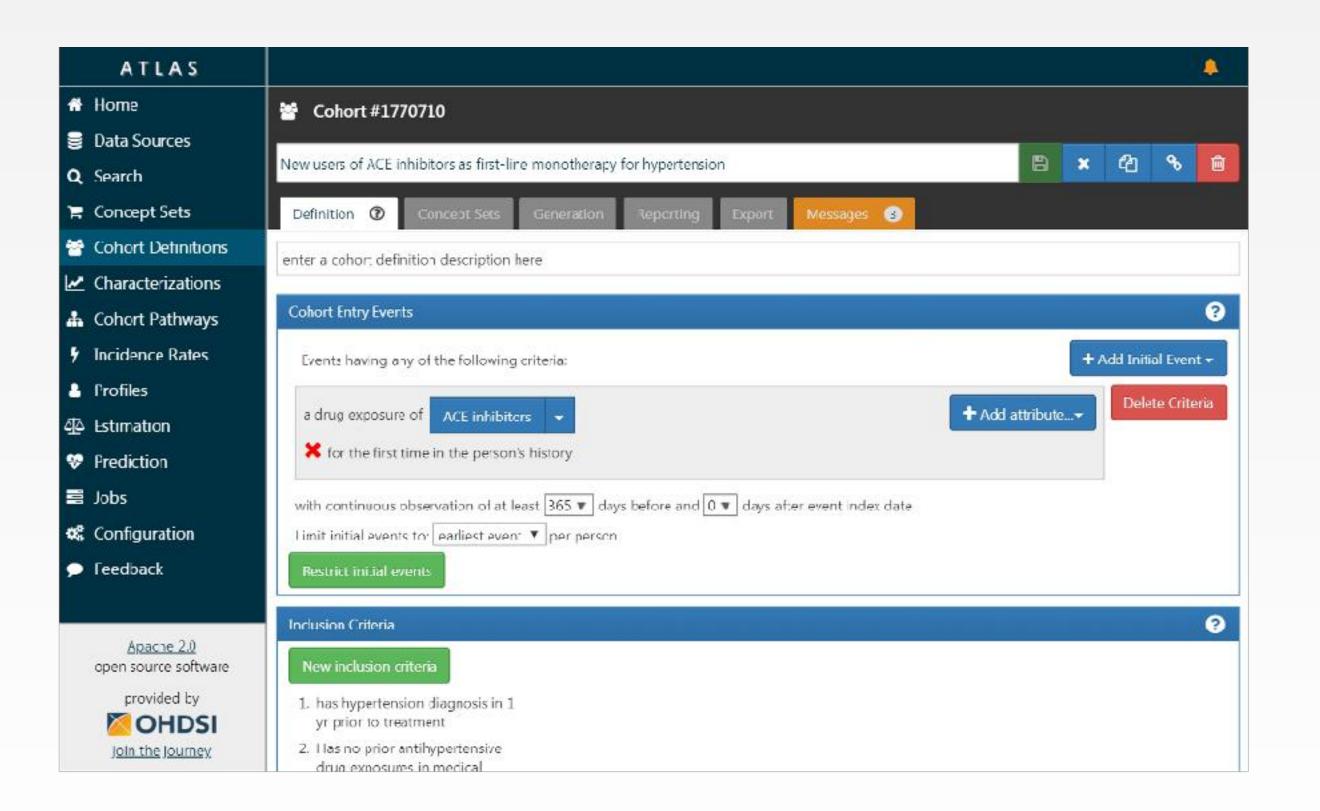






### **OHDSI Tools**

### Web-based Tool: ATLAS



### Code-based Tools: HADES



- +Evidence Quality
- +Cohort construction and evaluation
- +Characterization
- +Patient-level prediction
- +Population-level estimation



[ https://ohdsi.github.io/Hades/packages.html ]



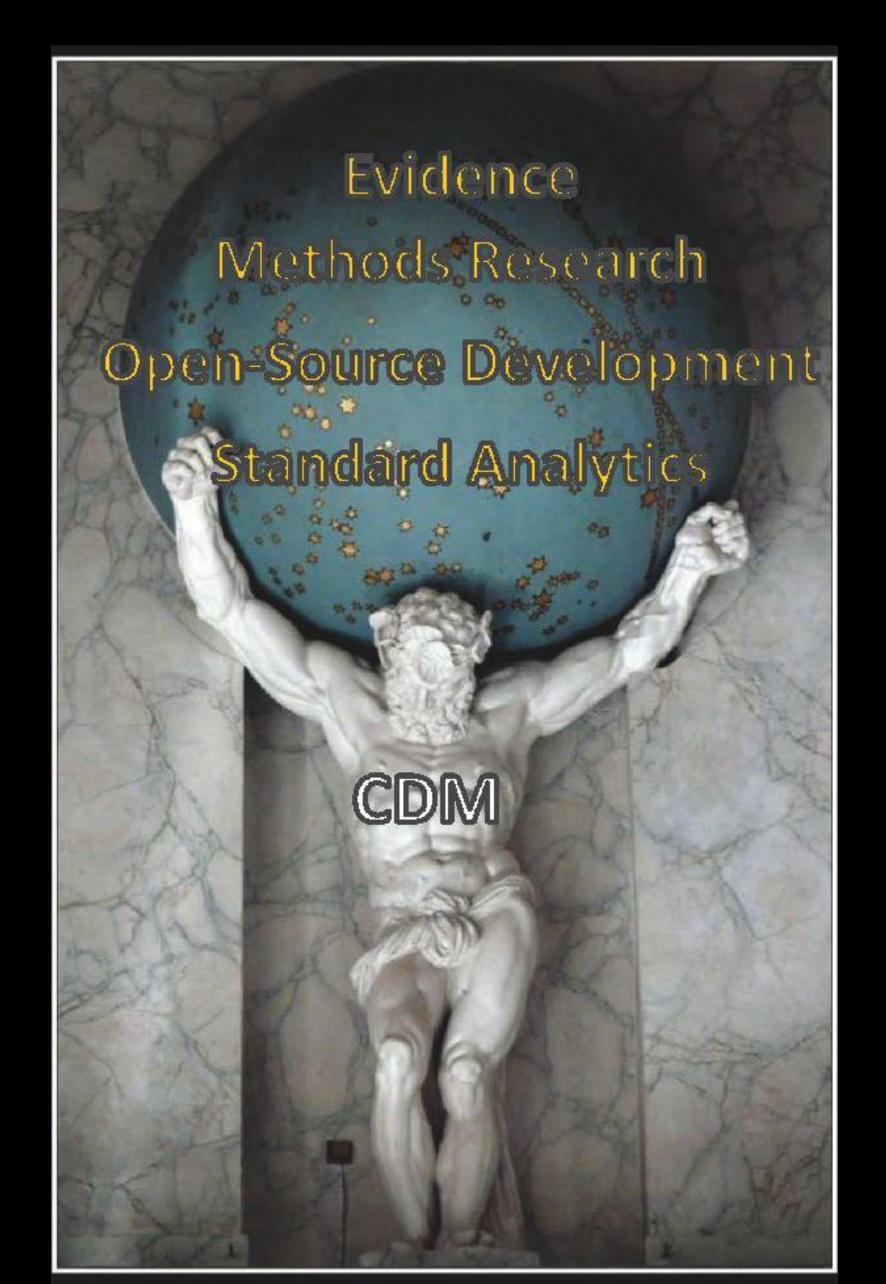
### Atlas

In Greek mythology, the Titan Atlas was responsible for bearing the weight of the heavens on his shoulders, a burden given to him as punishment by Zeus for leading the Titans in their battle with the Olympian Gods for control of the heavens. Father of many stars and a protagonist in one of Hercules' famous labors, Atlas was also known as a wise man and the founder of astronomy.

[ https://www.worldhistory.org/atlas ]

The term Atlas has been used to describe a collection of maps since the 16<sup>th</sup> century when Flemish geographer Gerardus Mercator published his work in honor of the mythological Titan.

[ https://en.wikipedia.org/wiki/Atlas\_(mythology) ]





### Hades

Hades was both the name of the ancient Greek god of the underworld (Roman name: Pluto) and the name of the shadowy place below the earth which was considered the final destination for the souls of the dead.

Following the overthrow of first the Titans and then the Giants by the Olympian gods, Hades drew lots with his brothers Zeus and Poseidon to decide which part of the world each would rule. Zeus received the sky, Poseidon the seas, and Hades the underworld.

[ https://www.worldhistory.org/Hades ]





### Where You Fit In

#### https://ohdsi.github.io/TheBookOfOhdsi/WhereToBegin.html

lam a clinical researcher looking to start a study. OHDSI loves to publish and has many resources available to expedite turning your research question into an analysis and a paper.

I am a database administrator
looking to ETL/convert my institution's
data to the OMOP CDM. If you're just
starting out on your ETL process, consult
the OHDSI Community ETL Tutorial
Slides or sign-up for the next offering at
an upcoming OHDSI Symposium.

I want to read and consume the information the OHDSI community produces. Whether you're a patient, a practicing clinician or subject matter expertise in healthcare, OHDSI wants to provide you with high quality evidence to help you better understand health outcomes.

I am a biostatistician and/or methods developer interested in contributing to the OHDSI tool stack. You're savvy in R. You know how to commit to Git. Most of all, you're eager to bring your expertise to the OHDSI Methods Library and further develop these methodologies. We welcome your contributions!

I work in a healthcare leadership role. I may be a data owner and/or represent one. I am evaluating the utility of the OMOP CDM and OHDSI analytical tools for my organization. More than 200 organizations around the world are collaborating in OHDSI, there's plenty of success stories to help showcase the value of this community.

I am a software developer interested in building a tool that complements the OHDSI tool stack. As part of the OHDSI mission, our tools are open source and governed under Apache licenses.

I am a consultant looking to advise the OHDSI
Community. You're invited to join us at OHDSI Tutorials and consider giving back by contributing your expertise in the Symposium proceedings and OHDSI face-to-face meetings throughout the year.

I am a student looking to learn more about OHDSI. You're in the right place! Consider joining an OHDSI Community Call and introducing yourself. You are encouraged to delve into the OHDSI tutorials, attend OHDSI Symposiums and face-to-face meetings to learn more about the methods and tools the OHDSI community offers.



#### How Healthcare Systems Can Create Value by Adopting the OMOP CDM

John Methot, Melanie Philofsky, Brian J. Bush, Paul Nagy, Daniel Smith, Edward Smith OHDSI Healthcare Systems Interest Group

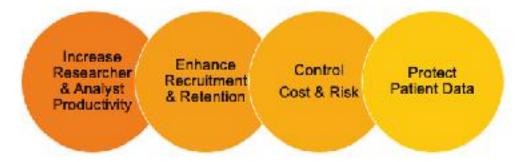


Poster: https://www.ohdsi.org/2022showcase-78/

#### Background

In the OHDSI community there is wide belief that adoption of OHDSI has significant benefits for healthcare systems in both operations and research. However, that hypothesis is currently "expert opinion". We describe here our plan to gather evidence on cost savings and other benefits that healthcare systems can realize by adopting the OMOP CDM. Our results can be used by researchers and IT staff as business justification for OMOP adoption.

The benefits fall into these categories:



#### Methods

- A recent OHDSI-wide survey of organizations with OMOP CDMs revealed that approximately 250 respondents are healthcare organizations
- This ongoing project is an activity of the Healthcare Systems Interest Group. We surveyed members of the working group to collect and rank a set of realized and expected benefits.
- Our next step is to field a survey of OHDSI community members to identify healthcare systems that have adopted OMOP and collect quantitative estimates of associated cost savings across their activities.
- After collecting and analyzing survey data, we will author a publication containing quantitative evidence of cost savings and other benefits that healthcare organization can realize by adopting the OMOP CDM.

#### Top 10 Candidate Healthcare System Benefits of OMOP CDM Adoption

- Common Data Model improves data analyst productivity by simplifying many representation decisions
- Training materials are freely available and have been accessed by thousands of individuals who form a talent pool for recruiting
- Reduce costly chart abstraction via automated mapping of EMR data
- Rich environment of available open-source analysis tools, both web-based and R
- Extensible for multi-model precision medicine research; can support EMRs, HIEs, Claims, Registries, IoT, etc.
- All patient data remains local: OHDSI supports a federated analysis model in which analysis code is shared, not data
- Supports reproducible research, based on CDM semantics and published analysis code
- Ability to easily participate in collaborative studies; examples are All of Us, N3C, numerous OHDSI network studies
- Easy deployment of the OHDSI technology stack on cloud infrastructure; supported by AWS, GCP and Microsoft Azure
- An ecosystem of vendors exists with expertise in OMOP infrastructure, ETL, and study design

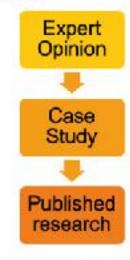
### Do you represent a healthcare system? Please take our survey!



https://bit.ly/OMOPAdopt

#### Results and Conclusions

- We produced a list of the top 10 benefits we hypothesize healthcare systems can realize from OMOP CDM adoption.
- We designed and fielded a survey to more accurately characterize healthcare system benefits.
- We used this poster and the 2022 OHDSI Global Symposium to advertise the survey and recruit respondents.



- We will aggregate and summarize the survey findings
- We will author a publication describing actual benefits realized by healthcare systems, advancing the topic from expert opinion to published research
- We will publicize the paper and promote its use as business justification for researchers and informatics staff seeking financial support for OMOP CDM adoption at their institutions

Authors: John Methot<sup>1</sup>, Melanie Philofsky<sup>2</sup>, Brian J. Bush<sup>3</sup>, Paul Nagy<sup>4</sup>, Daniel Smith<sup>5</sup>, Edward Smith<sup>6</sup>

<sup>1</sup>Dana-Farber Cancer Institute, <sup>2</sup>Odysseus Data Services, <sup>3</sup>Virginia Commonwealth University, <sup>4</sup>Johns Hopkins University, <sup>5</sup>Emory University, <sup>6</sup>University of Maryland Medical Center I work in a healthcare leadership role. I may be a data owner and/or represent one. I am evaluating the utility of the OMOP CDM and OHDSI analytical tools for my organization. More than 200 organizations around the world are collaborating in OHDSI, there's plenty of success stories to help showcase the value of this community.

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### Resources

- 1. The Book of OHDSI: https://ohdsi.github.io/ TheBookOfOhdsi
- 2. EHDEN Academy: https://academy.ehden.eu
- 3. OHDSI Past Events: https://www.ohdsi.org
- 4. OHDSI Community Calls: https://www.ohdsi.org/ community-calls/
- 5. OHDSI Forums: http://forums.ohdsi.org
- 6. YouTube: https://www.youtube.com/@OHDSI
- 7. Soon, Intro to OMOP in Thai :: https://omop.sidata.plus







#### Join the OHDSI forum

OHDSI Tip: Follow topics to receive emails when new posts are added

#### Introduce yourself!

Let the community know you're here by introducing yourself in the forum or at a community meeting

#### Join an OHDSI meeting

Sit in on our weekly community meetings







#### Join the OHDSI research network

By leading a study across the network

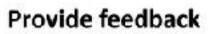
OR

By converting data to the OMOP Common Data Model

#### Join an working group

Or start your own work group!





Identify and evaluate ways to use real-world evidence to inform decision making



#### Join the Journey

Help improve medical decision making today!











# Inspiring Experience from Singapore

Asst. Prof. Mengling 'Mornin' Feng National University of Singapore









### Session Overview

Inspiring Experience from Singapore @ 10:45 – 11:15 (30 min)

Why? Background & Questions	How? Methods & Materials	What? Objectives
<ul> <li>☐ How do other countries/ systems adopt OMOP/ OHDSI?</li> <li>☐ What are their research products?</li> </ul>	<ul> <li>Recorded talk from OHDSI Singapore Chapter Updates mid-2023</li> <li>Live Q&amp;A session with Mornin</li> </ul>	<ul> <li>★ See Singapore's OMOP/ OHDSI adoption</li> <li>★ Get inspired to further explore the global community and research opportunities</li> </ul>



### Map of collaborators





### OHDSI APAC Local Chapters



#### OHDSI APAC - Our Asia-Pacific Community

OHDSI is a global, multi-stakeholder, interdisciplinary and open-science network that collaborates to bring out the value of health data through large-scale analytics. Our Asia-Pacific (APAC) community comprises seven regional chapters (Australia, China, India, Japan, Singapore, South Korea, Taiwan) and has led important OHDSI initiatives around the world.

#### **OHDSI APAC Community in Teams**

The APAC community has its own group in the OHDSI MS
Teams environment to promote greater collaboration on
our collaborative efforts. First, request access to our MS
Teams Environment, then request access to our OHDSI
APAC workgroup.

Date		Торіс	
Date		Юріс	
August 17	Europe	an and APAC Symposium Recap	
September 21		Training Session #5	
October 19		Training Session #6	
November 16	Global Symp	oosium Recap and Training Session #7	
December 21	APAG	2023 Recap and Year Closing	
@OHDSI	www.ohdsi.org	#JoinTheJourney	in of

#### **APAC Monthly Community Call**

Everybody is invited to the monthly OHDSI APAC community call, which takes place the third Thursday of each month at 12 pm Korea time. These calls are meant to provide updates, share research presentations, collaborate on topics of shared interest, and plenty more. The upcoming schedule is available to the right.

#### 2023 APAC Symposium

July 13-14 · University of New South Wales · Sydney, Australia



The 2023 OHDSI APAC Symposium was held July 13-14 in Sydney, Australia at the University of New South Wales. Thank you to all the volunteers who helped put together this fantastic event. Videos of all presentations are included below, while videos from the tutorials are coming soon!

#### **Symposium Presentations**

Welcome, Keynote



Speakers: Nicole Pratt (President OHDSI Australia Chapter, University of South Australia) and Patrick Ryan (Vice President, Observational Health Data Analytics, Janssen Research and Development) Transforming health: What do regulators, clinicians, and consumers really want to know about healthcare and how can OHDSI help



Speaker: Asieh Golozar (Vice President, Global Head of Data, Science at Odysseus Data Services, Inc. Professor of the Practice & Director of Clinical Research at the OHDSI Center, Northeastern University)



### **OHDSI Singapore**





#### Co-Chairs:

Dr. Mengling 'Mornin' Feng
Senior Assistant Director, National University Health System
Assistant Professor, National University of Singapore
ephfm@nus.edu.sg



Dr. Kee Yuan Ngiam

Group Chief Technology Officer

National University Health System









### OHDSI Tools: Athena & Atlas









### Session Overview

OHDSI Tools: Athena & Atlas @ 11:15 – 12:00 (45 min)

Why?	How?	What?
Background & Questions	Methods & Materials	Objectives
<ul> <li>☐ How do OMOP record medical concepts? ICD-10/ICD-9? SNOMED?</li> <li>☐ How can we browse standard codes on Athena?</li> <li>☐ How can we use OMOP CDM via website, Atlas?</li> </ul>	<ul> <li>Overview of Standard Concepts</li> <li>Features of Athena &amp; Atlas</li> <li>Hands-on: Vocabulary search in Athena</li> <li>Hands-on: Log-in to Atlas</li> </ul>	<ul> <li>★ Learn how to navigate Athena &amp; Atlas</li> <li>★ Acquire practical experience through hands-on exercises</li> </ul>

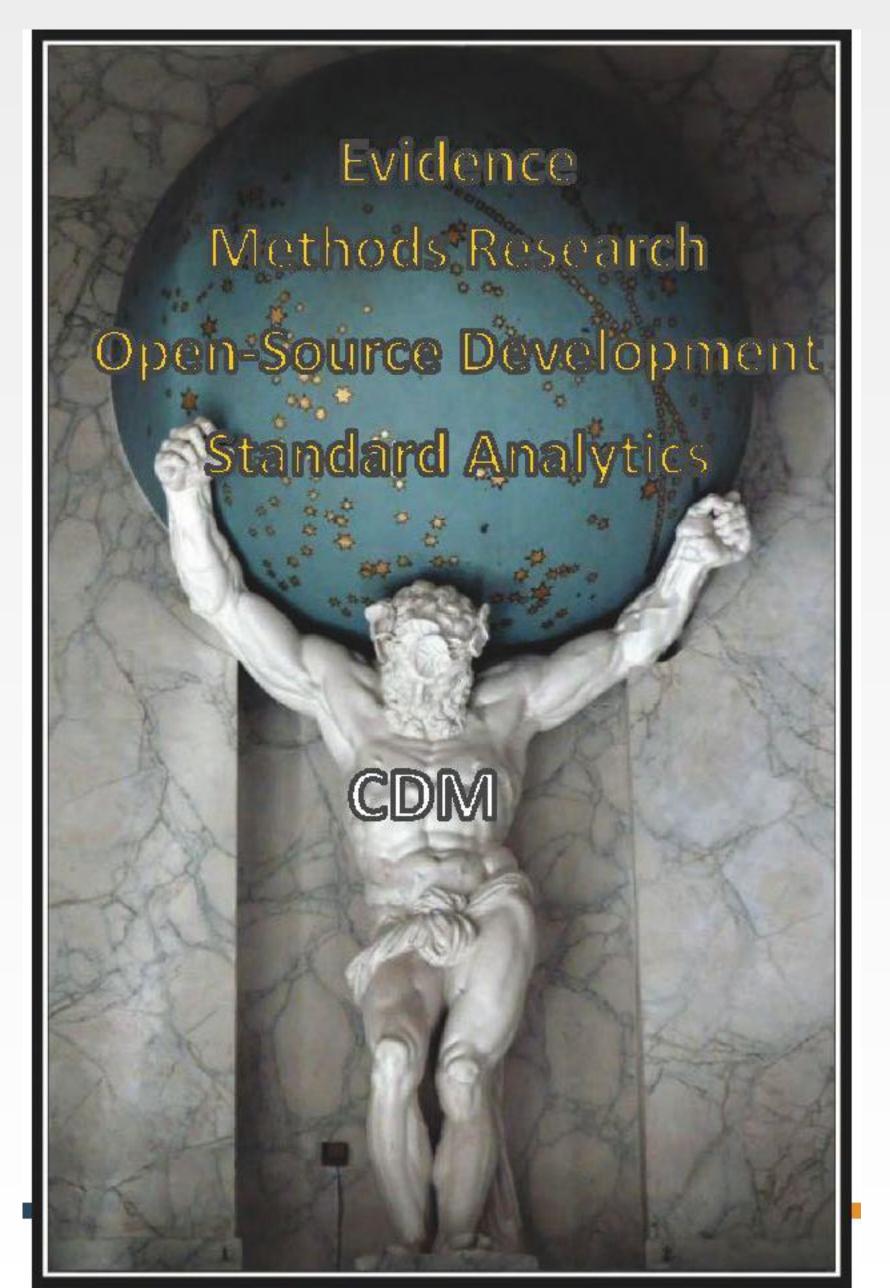




### OMOP CDM

The OMOP CDM is a system of tables, vocabularies, and conventions that allow observational health data to be standardized.

It is this standard approach that facilitates rapid innovation in the areas of open-source development, methods research, and evidence generation.

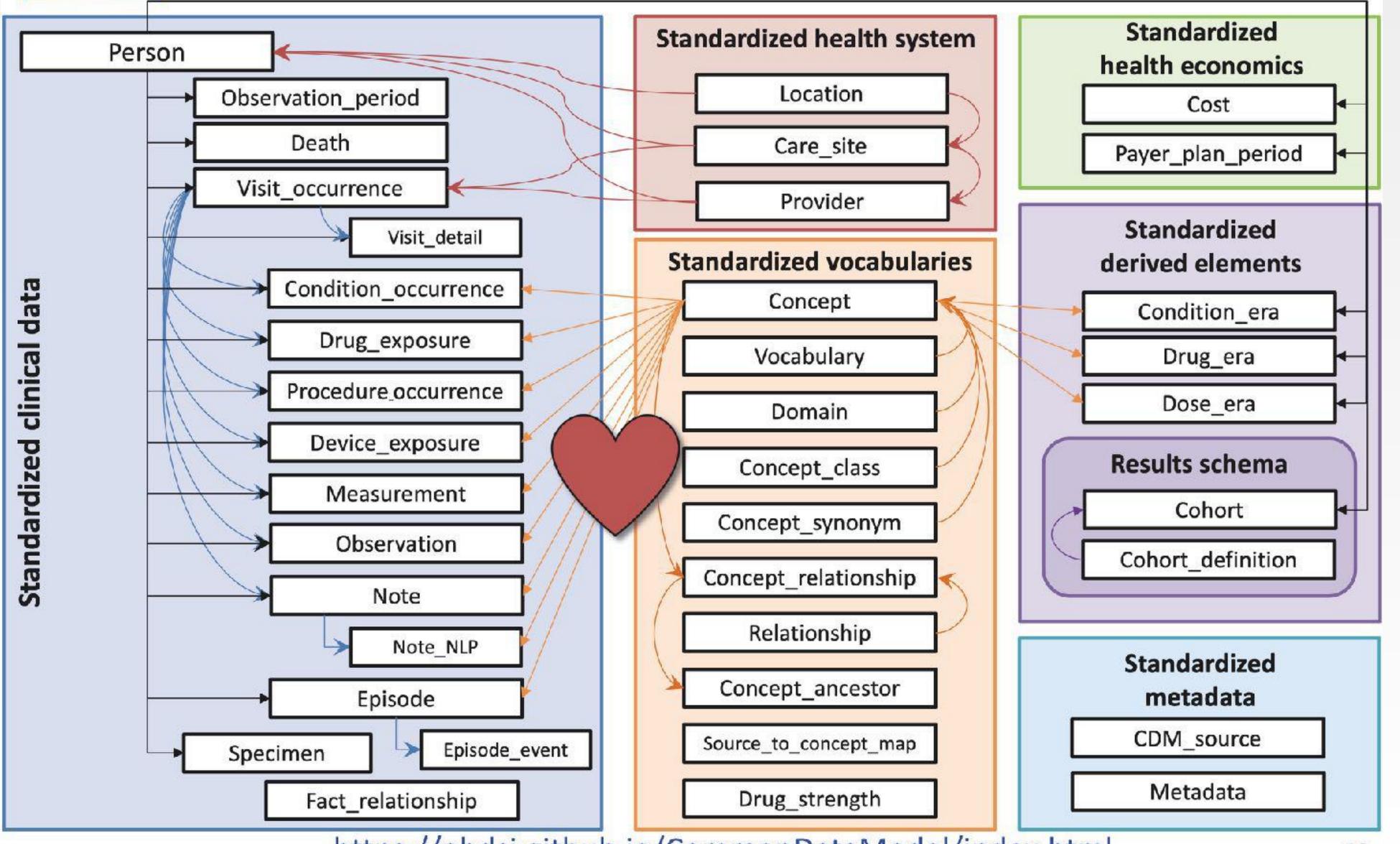






### OMOP CDM & Vocabulary







### Different Categories of Concepts









#### **Function**

Unique representation of a source code

e.g., ICD-10, TMT, TMLT

#### **Function**

Used for standardized analytics and by OHDSI tools

e.g., SNOMED, RxNorm, LOINC

#### **Function**

Used to perform hierarchical queries

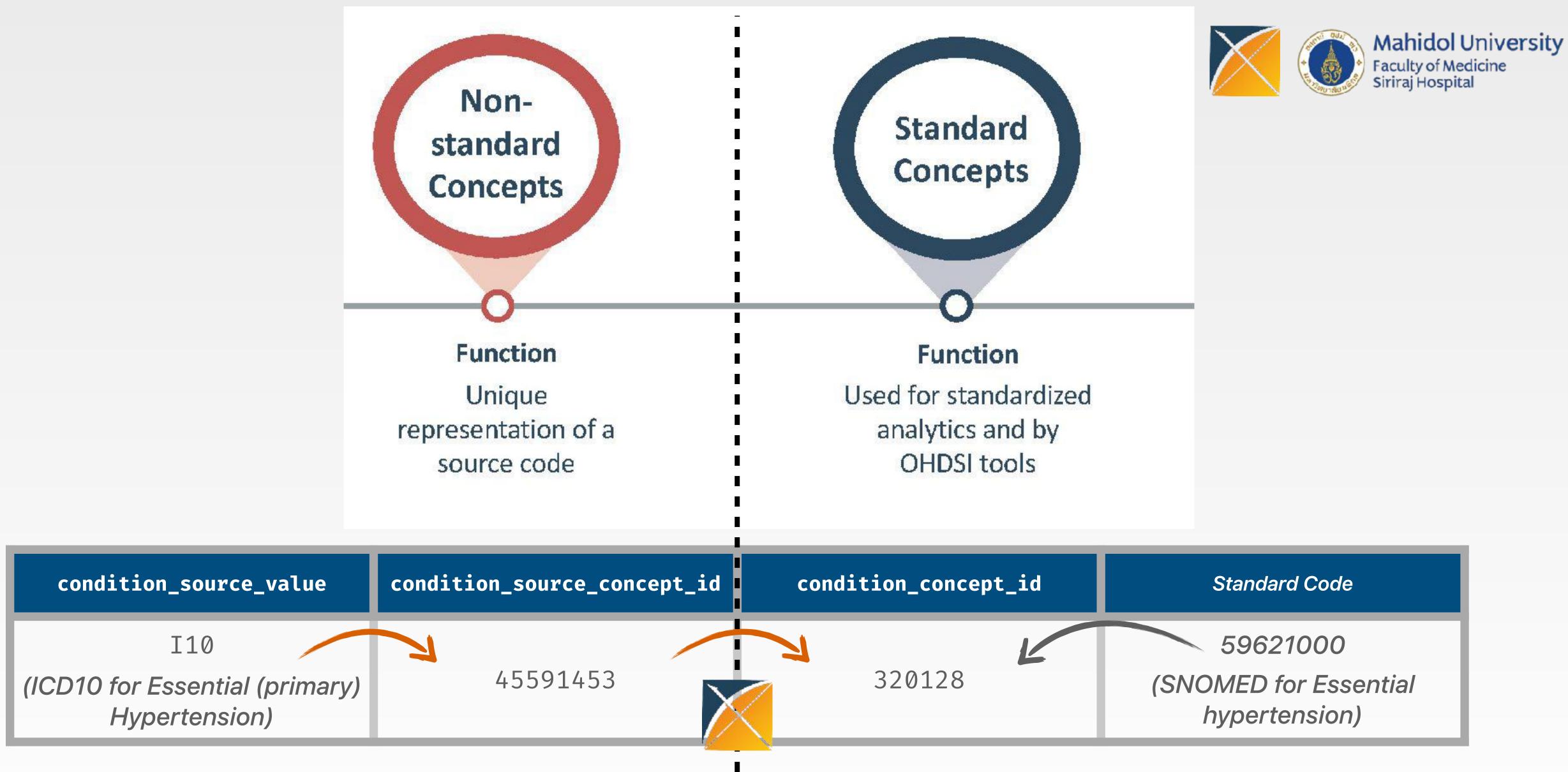
e.g., drug groups, dx groups



### Standard Concepts

#### https://ohdsi.github.io/TheBookOfOhdsi/StandardizedVocabularies.html

Table 5.2: List of vocabularies to utilize for Standard/non-standard/classification concept assignments.				
Domain	for Standard Concepts	for source concepts	for classification concepts	
Condition	SNOMED, ICDO3	SNOMED Veterinary	MedDRA	
Procedure	SNOMED, CPT4, HCPCS, ICD10PCS, ICD9Proc, OPCS4	SNOMED Veterinary, HemOnc, NAACCR	None at this point	
Measurement	SNOMED, LOINC	SNOMED Veterinary, NAACCR, CPT4, HCPCS, OPCS4, PPI	None at this point	
Drug	RxNorm, RxNorm Extension, CVX	HCPCS, CPT4, HemOnc, NAAACCR	ATC	
Device	SNOMED	Others, currently not normalized	None at this point	
Observation	SNOMED	Others	None at this point	
Visit	CMS Place of Service, ABMT, NUCC	SNOMED, HCPCS, CPT4, UB04	None at this point	

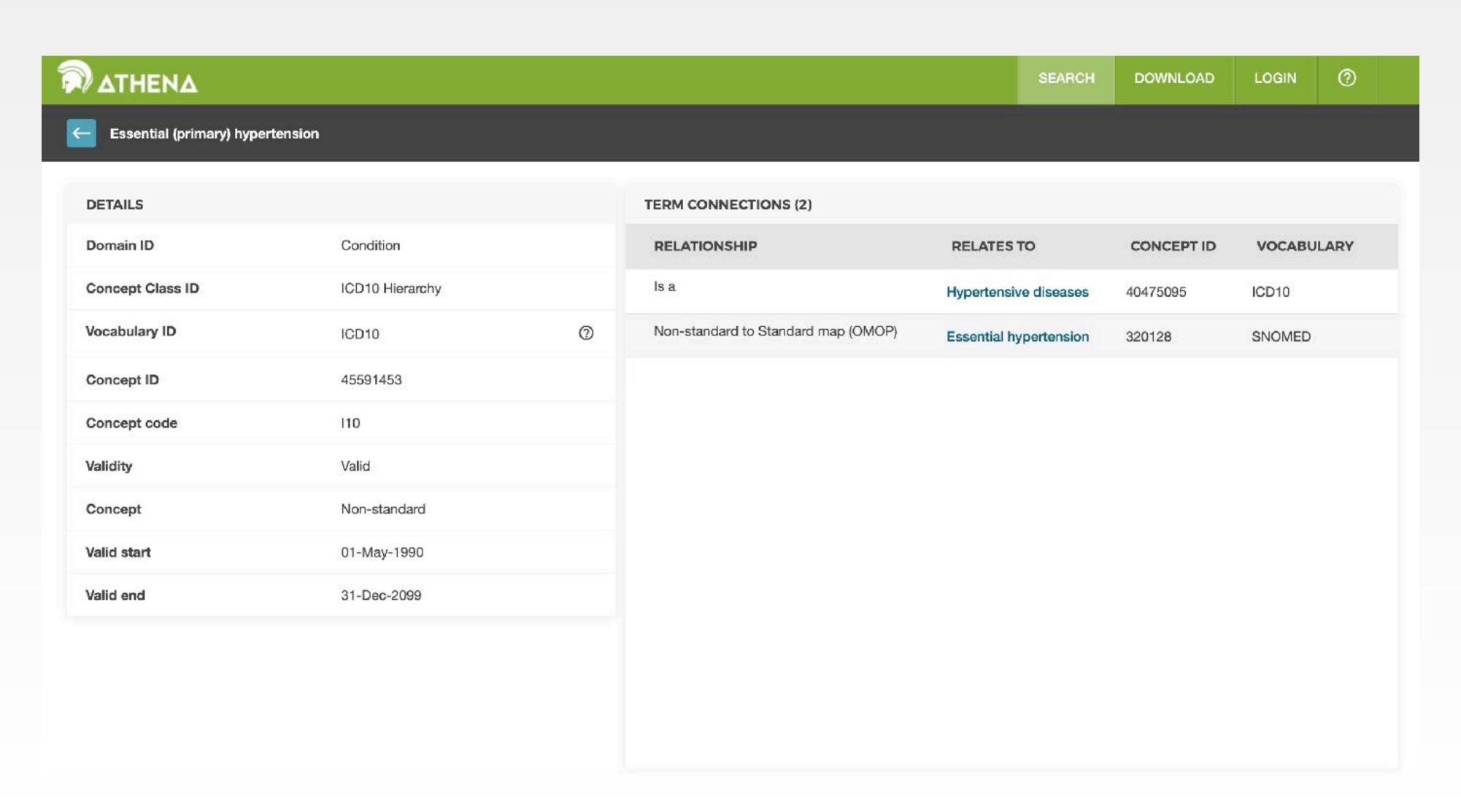


- \_source\_value รหัสโรค/หัตถการ/ยา/แลป/อื่น ๆ ต้นทาง
- \_source\_concept\_id รหัสโรค/หัตถการ/ยา/แลป/อื่น ๆ ต้นทาง ที่ mapped เป็น ID ของ OMOP
- \_concept\_id รหัสโรค/หัตถการ/ยา/แลป/อื่น ๆ standard ที่ mapped เป็น ID ของ OMOP



### Demo: 110 Hypertension

https://athena.ohdsi.org/search-terms/terms/45591453



## Hands-on: Find standard concept for 148 Atrial Fibrillation

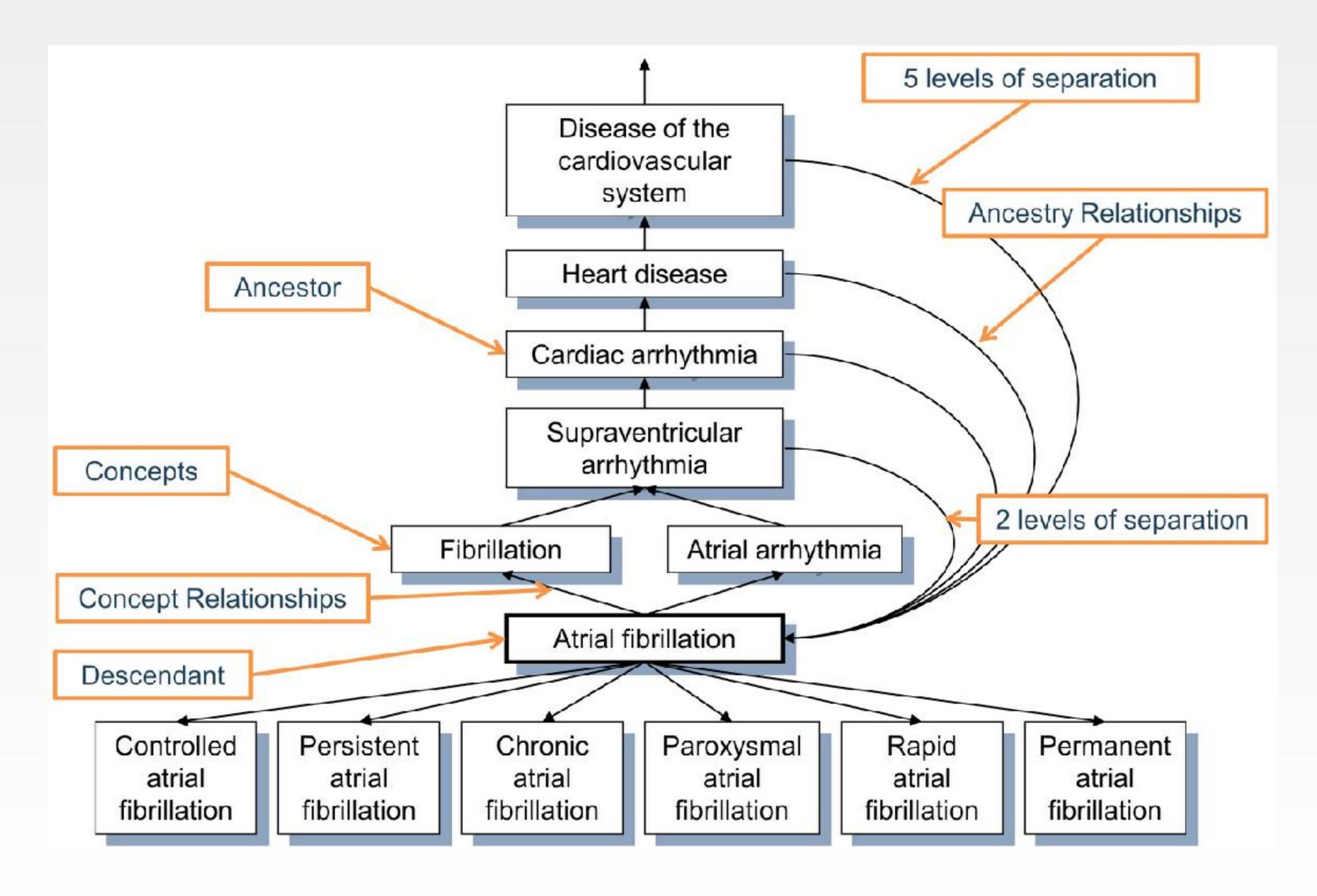


https://athena.ohdsi.org

ATHENA						SEA	RCH DO	WNLOAD	LOGIN	@	
SEARCH BY KEYWORD		i48								Q	?
i48 ×		DOWNL	OAD RESULTS				Sho	w by 15	items	Total 6 ite	ems
DOMAIN	•	ID ▼	CODE ▼	NAME ▼	CLASS W	CONCEPT ▼	VALIDITY	DOM	IAIN 🔻	VOCAB	₩
• CONCEPT	•	45596206	148	Atrial fibrillation and flutter	ICD10 Hierarchy	Non-standard	Valid	Cond	dition	ICD10	
• CLASS	•	1569170	148	Atrial fibrillation and flutter	3-char nonbill code	Non-standard	Valid	Cond	dition	ICD10CM	1
• VOCAB	•	1414209	148	Atrial fibrillation and flutter	ICD10 Hierarchy	Non-st				ICD10CN	ſ
• VALIDITY	*	37084653	148	Atrial fibrillation and flutter	ICD10 Hierarchy	Non-st				ICD10GM	1
		42488510	148	Atrial fibrillation and flutter	KCD7 code	Non-st				KCD7	
		37613128	148	Atrial fibrillation and flutter	ICD10 Hierarchy	Non-st				CIM10	
							7				
						7.76					



### Hierarchy



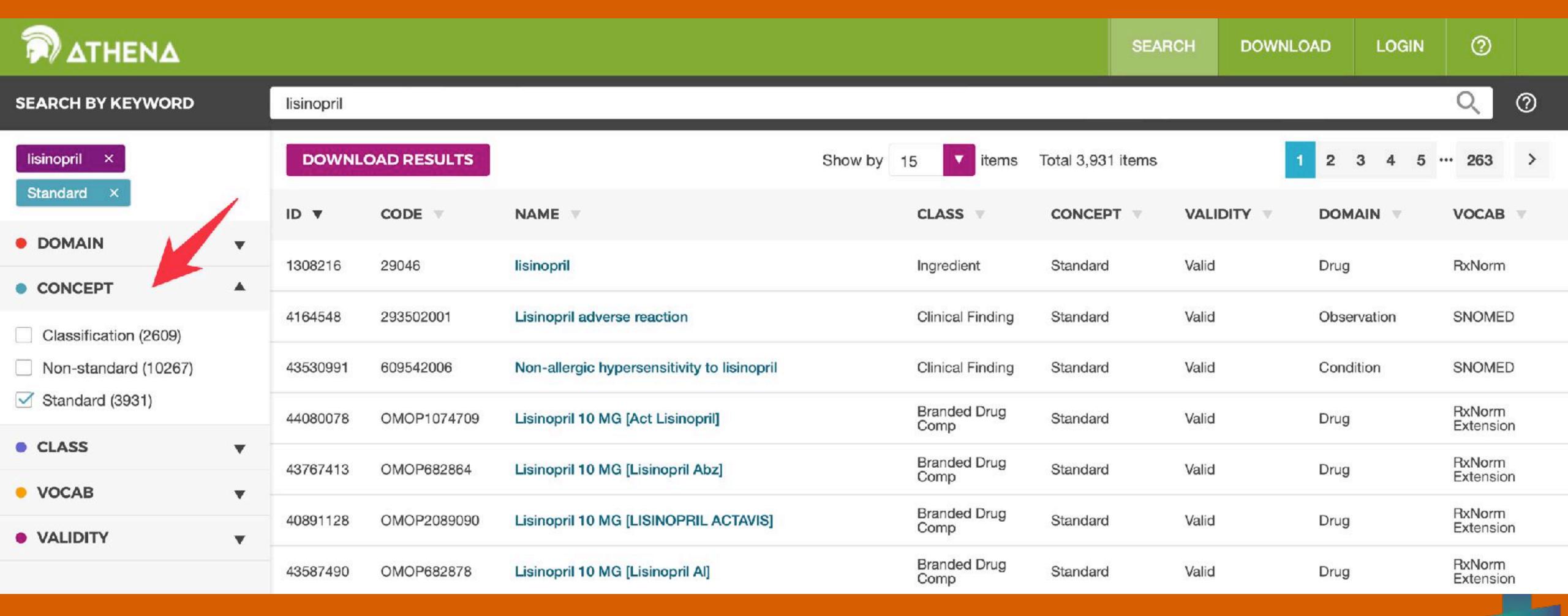




Mahidol University
Faculty of Medicine
Siriraj Hospital

### Hands-on: Find standard concept for Lisinopril\*

https://athena.ohdsi.org — Hint: filter only standard concept on the left panel





### Athena

Athena was the goddess of wisdom, war, and the crafts. She was the favorite daughter of Zeus and was, perhaps, the wisest, most courageous, and certainly the most resourceful of the Olympian gods.

Athena is credited with giving Odysseus the idea of the Wooden Horse in the Trojan War.



[ https://www.worldhistory.org/athena/ ]

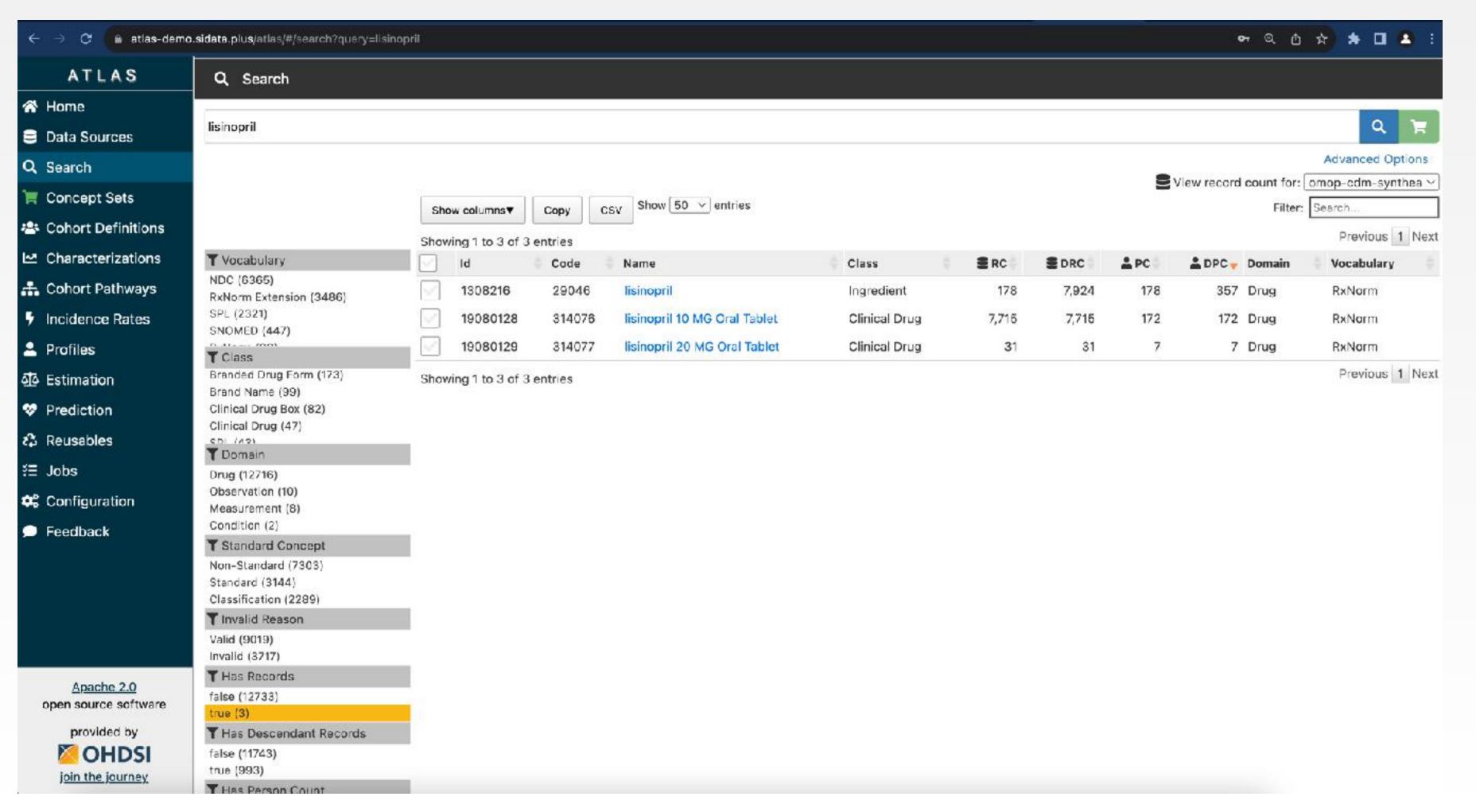
58



### Demo: Find Lisinopril on Atlas

https://atlas-demo.sidata.plus/atlas

backup: https://atlas-demo.ohdsi.org/, https://atlas.ohdsi.org/





### Concept Set Expressions

- Concept Set: logical expression to represent a list of concepts in the OHDSI vocabularies encompassing a clinical entity of interest
  - List of one or more concepts
  - Optional operator for each concepts in the list:
    - Exclude: Exclude this concept (and any of its descendants if selected) from the concept set.
    - Descendants: Consider not only this concept, but also all of its descendants.
    - Mapped: Allow to search for non-standard concepts.
- Concept Set can be thought of as a standardized, computer-executable equivalent
  of the code lists often used in observational studies.
- A concept set expression can be materialized into a list of concepts using any instance of the OHDSI vocabularies
  - JSON expression executed via webAPI into standard SQL query

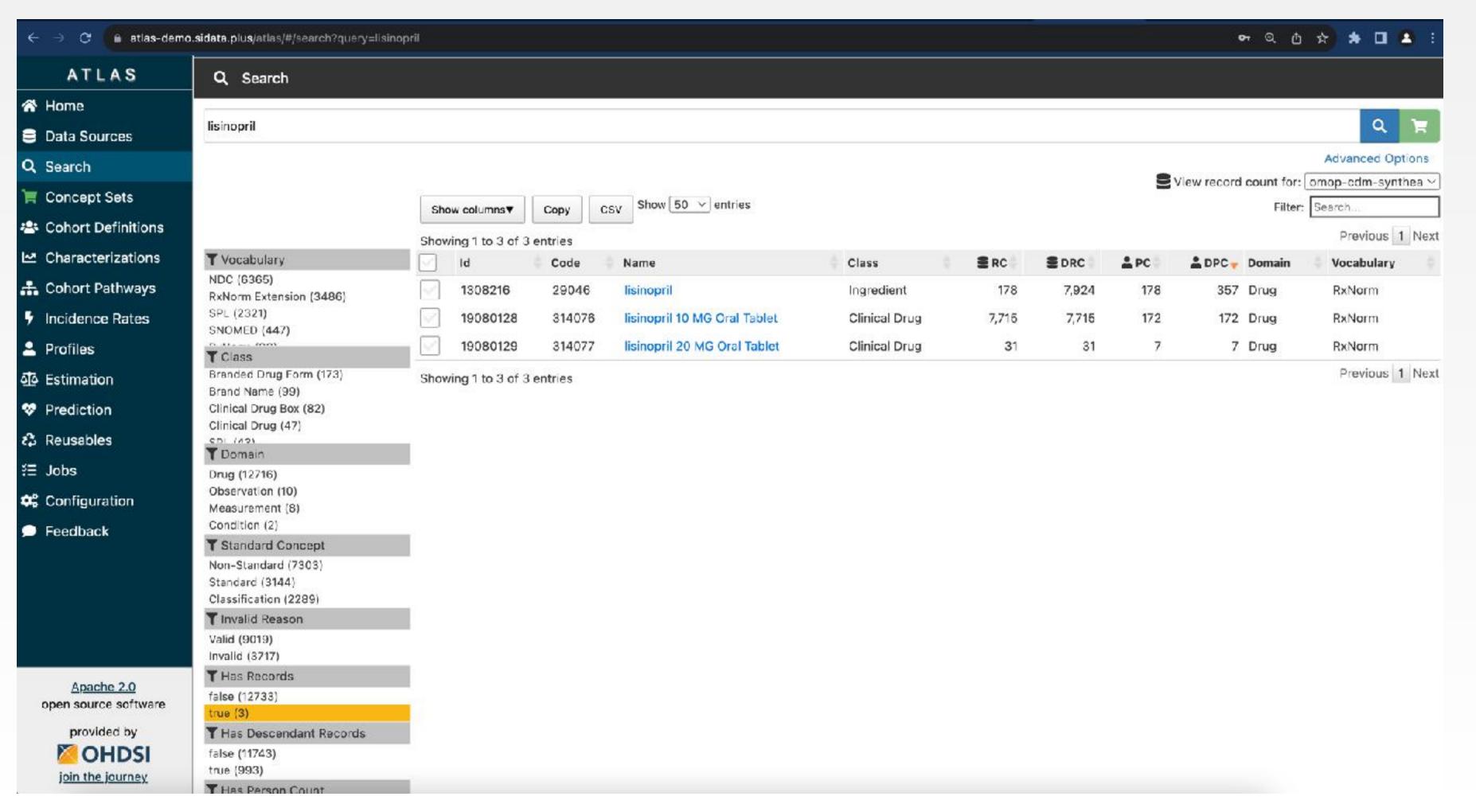




### Demo: Create concept set for Lisinopril

https://atlas-demo.sidata.plus/atlas

backup: https://atlas-demo.ohdsi.org/, https://atlas.ohdsi.org/

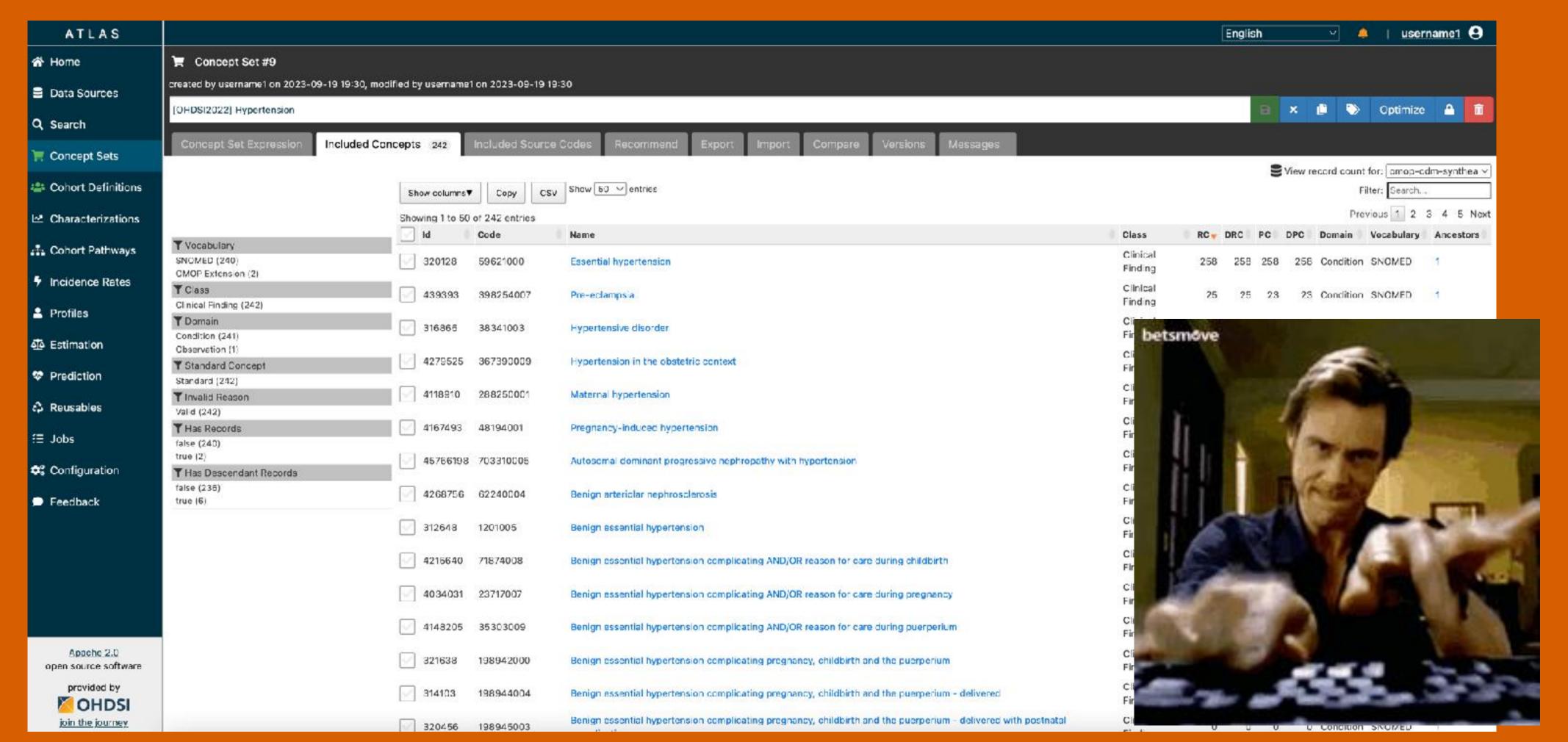




### Hands-on: Create concept set for Hypertension

https://atlas-demo.sidata.plus/atlas

backup: https://atlas-demo.ohdsi.org/, https://atlas.ohdsi.org/









# OHDSI Tools: Cohort Definition & Characterization









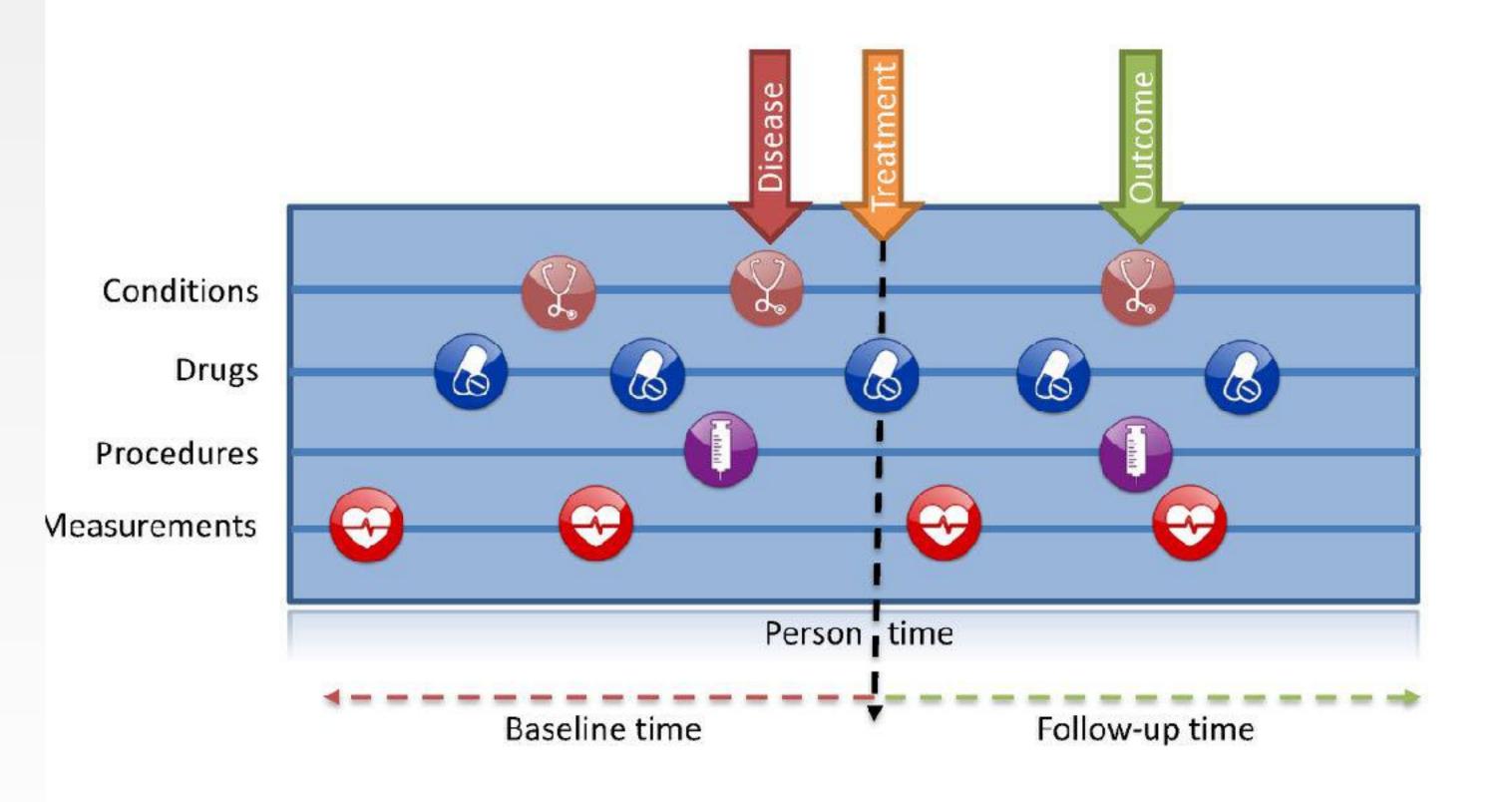
### Session Overview

OHDSI Tools: Cohort Definition & Characterization @ 13:00 – 14:30 (90 min)

Why? Background & Questions	How? Methods & Materials	What? Objectives
<ul> <li>What is a cohort?</li> <li>How can we specify research cohorts on Atlas? using Phenotype?</li> <li>Can we do basic descriptive statistical analyses on cohorts?</li> </ul>	<ul> <li>Basics of cohort definition, phenotype</li> <li>Hands-on: Defining a cohort using Atlas</li> <li>Hands-on: Cohort characterization with Atlas</li> <li>Most of slides from OHDSI2022 Tutorial sessions 3–5: <a href="https://www.ohdsi.org/ohdsi2022-tutorial/">https://www.ohdsi.org/ohdsi2022-tutorial/</a></li> </ul>	<ul> <li>★ Grasp the principles of cohort definition and characterization</li> <li>★ Practical exercise in defining and characterizing cohorts using Atlas</li> <li>★ Take home: Importance and practical know-how of cohort analytics</li> </ul>

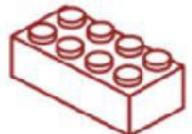


### Data are Like Lego Bricks for Phenotyping





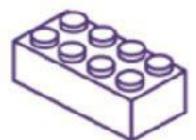
Conditions



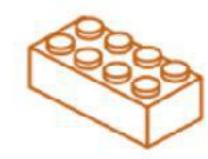
**Drugs** 



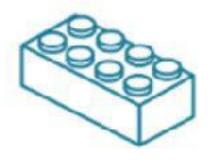
**Procedures** 



Measurements



**Observations** 



Visits

# The common building block of all observational analysis: cohorts

#### Required inputs:

Target cohort:
Person
cohort start date
cohort end date

Comparator cohort:
Person
cohort start date
cohort end date

Outcome cohort:
Person
cohort start date
cohort end date

#### **Desired outputs:**

Clinical characterization

Baseline summary of exposures

(treatment utilization)

Clinical characterization

Baseline summary of outcome
(disease natural history)

Incidence summary
Proportion/rate of outcome
occurring during time-at-risk for exposure

Population-level effect estimation Relative risk (HR, OR, IRR) of outcome occurring during time-at-risk for exposure

Patient-level prediction

Probability of outcome occurring during time-at-risk for each patient in population



### Defining 'phenotype'

Journal of the American Medical Informatics Association, 0(0), 2017, 1–6

doi: 10.1093/jamia/ocx110 Perspective





#### Perspective

#### High-fidelity phenotyping: richness and freedom from bias

#### George Hripcsak<sup>1</sup> and David J Albers<sup>1</sup>

- A phenotype is a specification of an observable, potentially changing state of an organism (as distinguished from the genotype, derived from genetic makeup).
- The term phenotype can be applied to patient characteristics inferred from electronic health record (EHR) data.
- The goal is to draw conclusions about a target concept based on raw EHR data, claims data, or other clinically relevant data.
- Phenotype algorithms ie, algorithms that identify or characterize phenotypes may
  be generated by domain exerts and knowledge engineers, or through diverse forms of
  machine learning to generate novel representations of data.



# Combining billing codes, clinical notes, and medications from electronic health records provides superior phenotyping performance

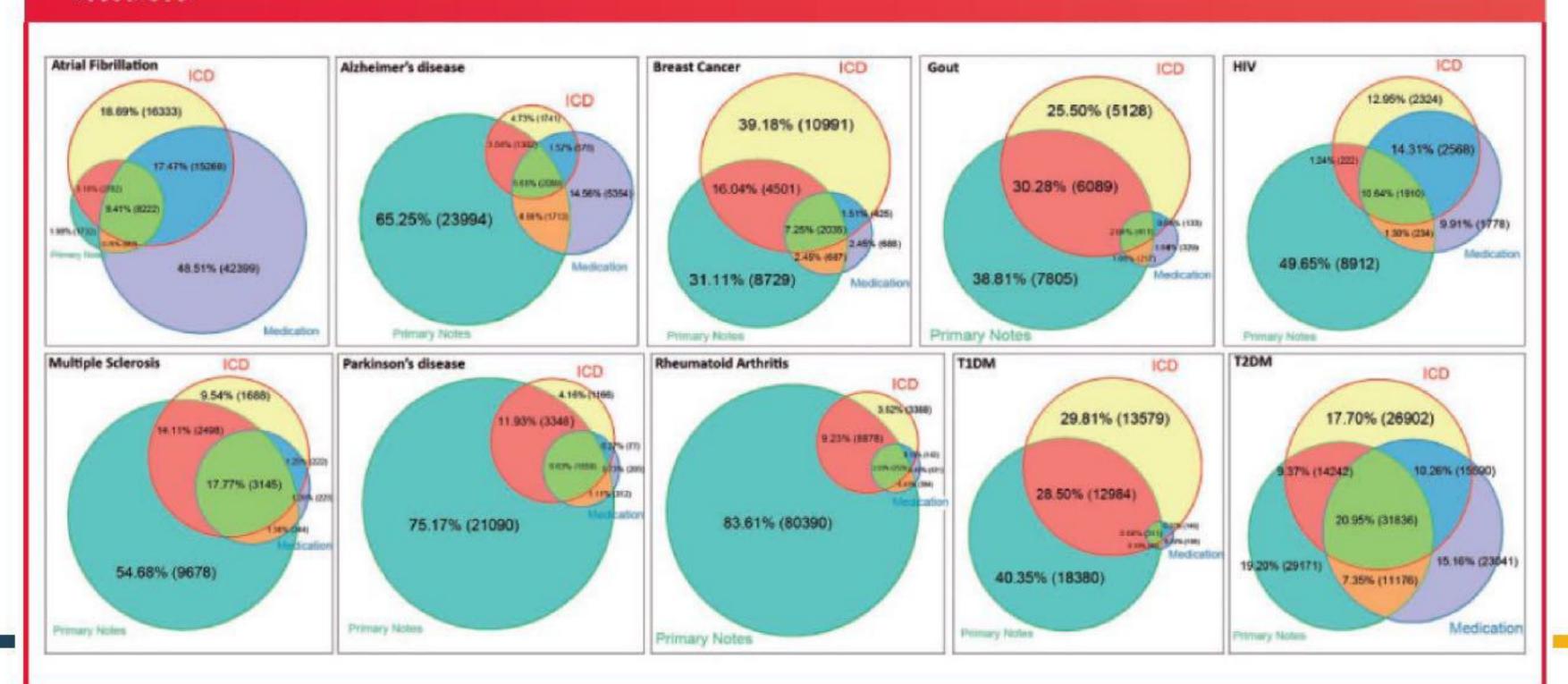
RECEIVED 8 January 2015
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PUBLISHED ONLINE FIRST 2 September 2015



OXFORD UNIVERSITY PRESS

Wei-Qi Wei<sup>1</sup>, Pedro L Teixeira<sup>1</sup>, Huan Mo<sup>1</sup>, Robert M Cronin<sup>1,2</sup>, Jeremy L Warner<sup>1,2</sup>, Joshua C Denny<sup>1,2</sup>

Figure 1: Weighted Venn diagrams of the distributions of patients with ICD-9, primary notes, and specific medications. Each color represents a resource. Different area colors represent the number of patients that were found within intersecting resources.





### OHDSI Phenotype Phebruary

https://www.ohdsi.org/phenotype-phebruary-2023/

- Feb. 1 Type 2 Diabetes Mellitus
- Feb. 2 · Type 1 Diabetes Mellitus
- Feb. 3 · Atrial Fibrillation
- Feb. 4 Multiple Myeloma
- Feb. 5 · Alzheimer's Disease
- Feb. 6 · Hemorrhagic Events
- Feb. 7 · Neutropenia
- Feb. 8 · Kidney Stones
- Feb. 9 · Delirium
- Feb. 10 Systemic Lupus Erythematosus
- Feb. 11 · Suicide Attempts
- Feb. 12 Parkinson's Disease and Parkinsonism
- Feb. 13 · Attention Deficit Hyperactivity Disorder
- Feb. 14 Hypertension (Video Description)
- Feb. 15 · Acute Myocardial Infarction
- Feb. 16 · Heart Failure
- Feb. 17 · Cardiomyopathy
- Feb. 18 · Multiple Sclerosis
- Feb. 19 · Triple Negative Breast Cancer
- Feb. 20 · Pulmonary Hypertension
- Feb. 21 · Prostate Cancer
- Feb. 22 · HIV
- Feb. 23 · Hidradenitis Suppurativa
- Feb. 24 · Anaphylaxis
- Feb. 25 · Depression
- Feb. 26 · Non-Small-Cell Lung Cancer
- Feb. 27 · <u>Drug-Induced Liver Injury</u>
- Feb. 28 · Severe Visual Impairment And Blindness
- Bonus · Acute Kidney Injury

#### Phenotype Phebruary 2023: How To Join The Effort

"Phenotype Phebruary" was a community-wide initiative to both develop and evaluate phenotypes for health outcomes that could be investigated by the community.

This is the second year of Phenotype Phebruary in the OHDSI community (look back at Year 1 here). It was introduced during the Jan. 31 community call (watch here), and went on throughout the month. This year, the leadership team of Gowtham Rao and Azza Shoaibi helped identify 11 phenotypes that are being investigated throughout the month. Though the month has ended, the work continues. If you would like to join the discussions around any of the phenotypes, please visit the appropriate links below, which will take you to the proper threads on the OHDSI forums.

#### What Did We Accomplish?



#### Phenotype Phebruary 2023 in numbers

- 11 phenotypes discussed in the forums
  - 5 phenotypes finished peer review --> library
- 5 phenotypes developed, evaluated and on their way to peer review
- 4 debates/discussions addressed
- 7 shiny apps on data.ohdsi.org
- 32 collaborators interacted in the forums or attended calls
- 9 Publications
- 8 applied publications planned
- 1 methods publication



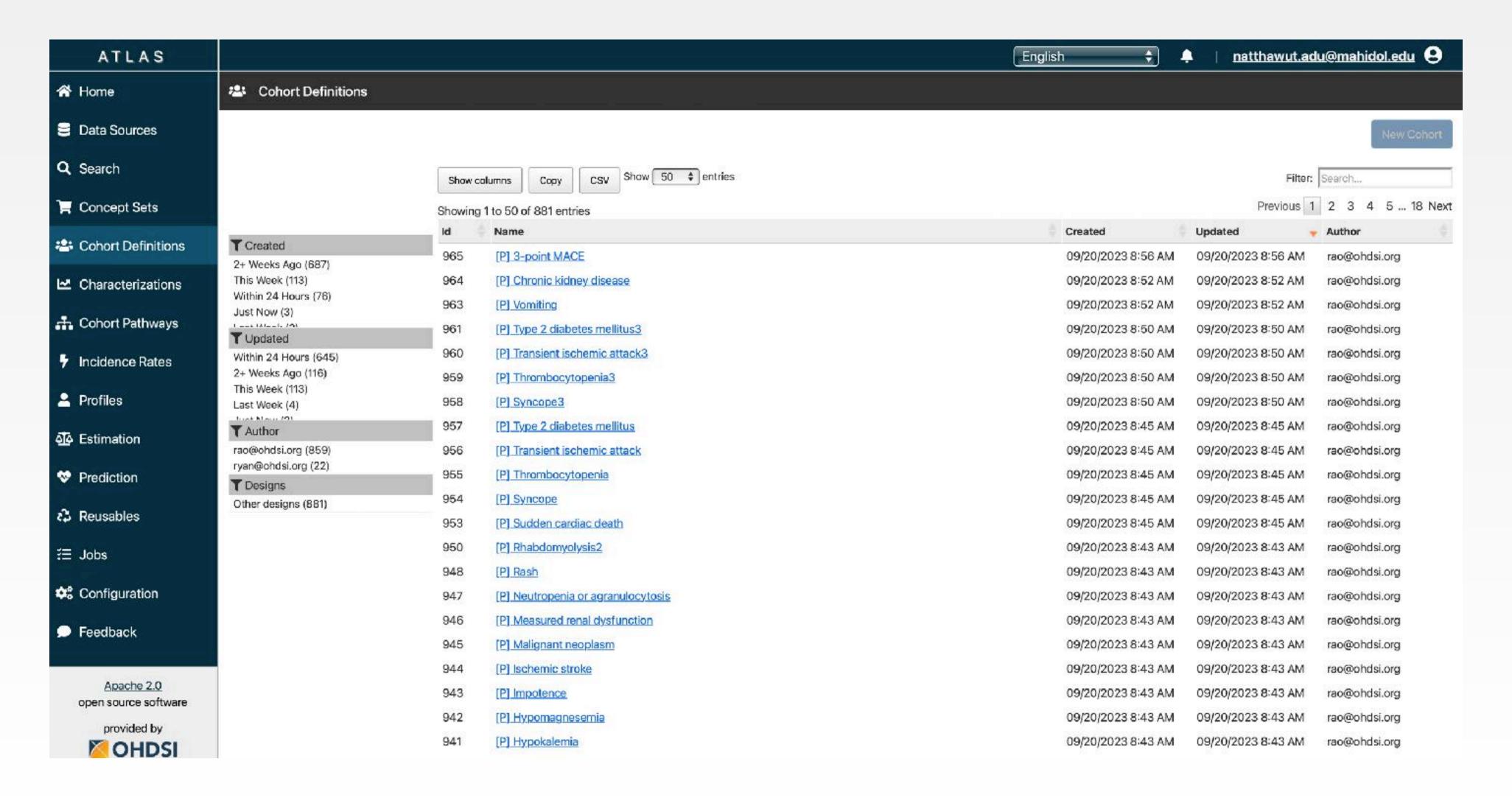
#### Join Our Community Efforts Around Any Of These Phenotypes

Announcements and Meeting/Workshop Links	Acute Pancreatitis	Anaphylaxis	Appendicitis	
Acquired Neutropenia	Systemic Lupus Erythematosus  Acute Hepatic Failure		Idiopathic Inflammatory Myopathies	
Parkinson's Disease	ST Elevation Myocardial Infarction	Neonatal Hypoxic Ischemic Encephalopathy	Neurofibromatosis type 1 with Optical Pathway Glioma	



### OHDSI Phenotype Library on Atlas

https://atlas-phenotype.ohdsi.org/





## Cohorts: The common building block of all observational analysis

- OHDSI's definition of 'cohort': Cohort is a set of persons who satisfy one or more inclusion criteria for a duration of time
- Cohort era: a continuous period during which a person has satisfied a cohort's inclusion criteria
- Cohort definition: the specification for how to identify a cohort

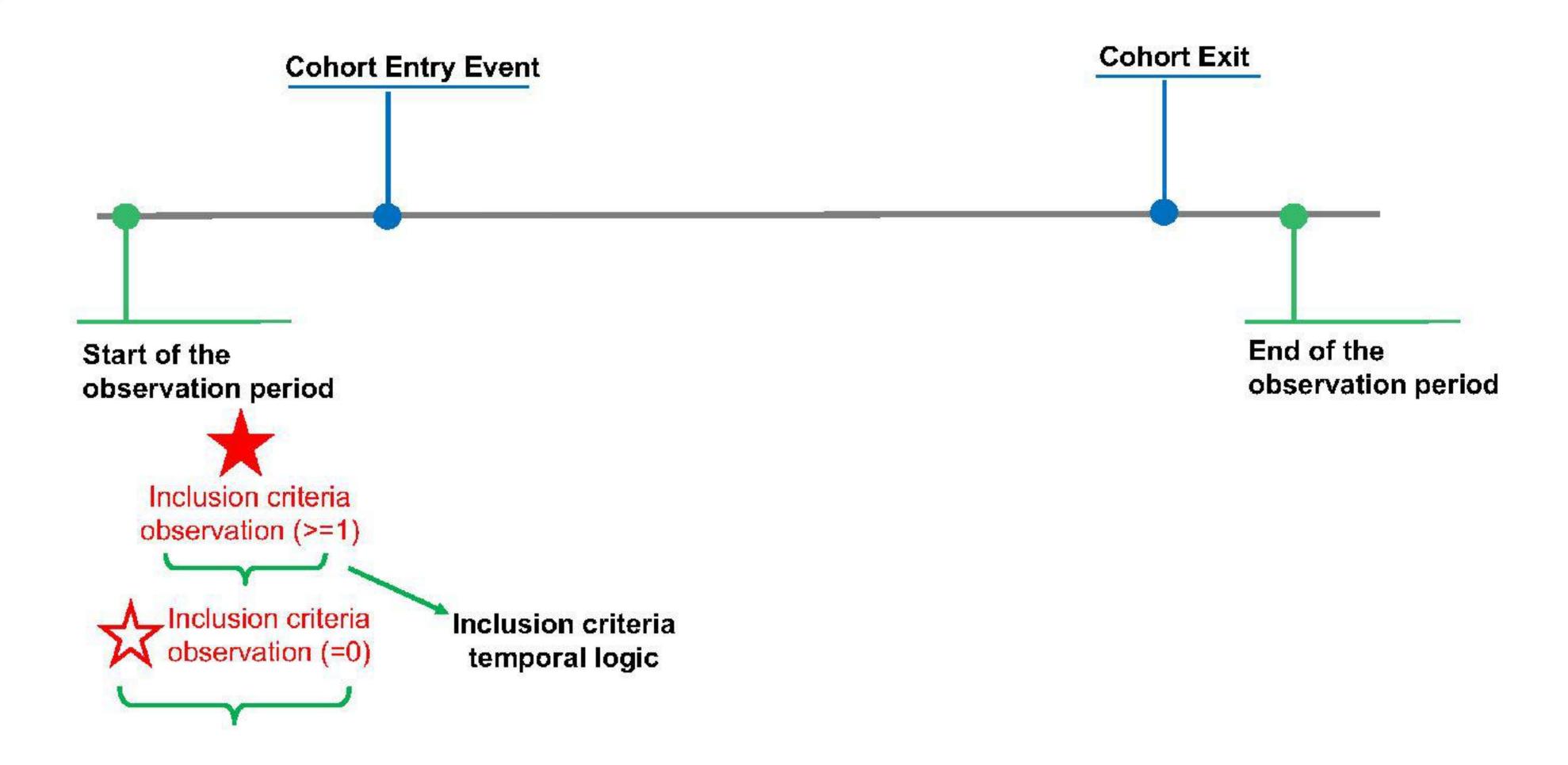
Objective consequences based on this cohort definition:

- One person may belong to multiple cohorts
- One person may belong to the same cohort at multiple different time periods
- One person may not belong to the same cohort multiple times during the same period of time
- One cohort may have zero or more members
- A codeset is NOT a cohort...

...logic for how to use the codeset in a criteria is required

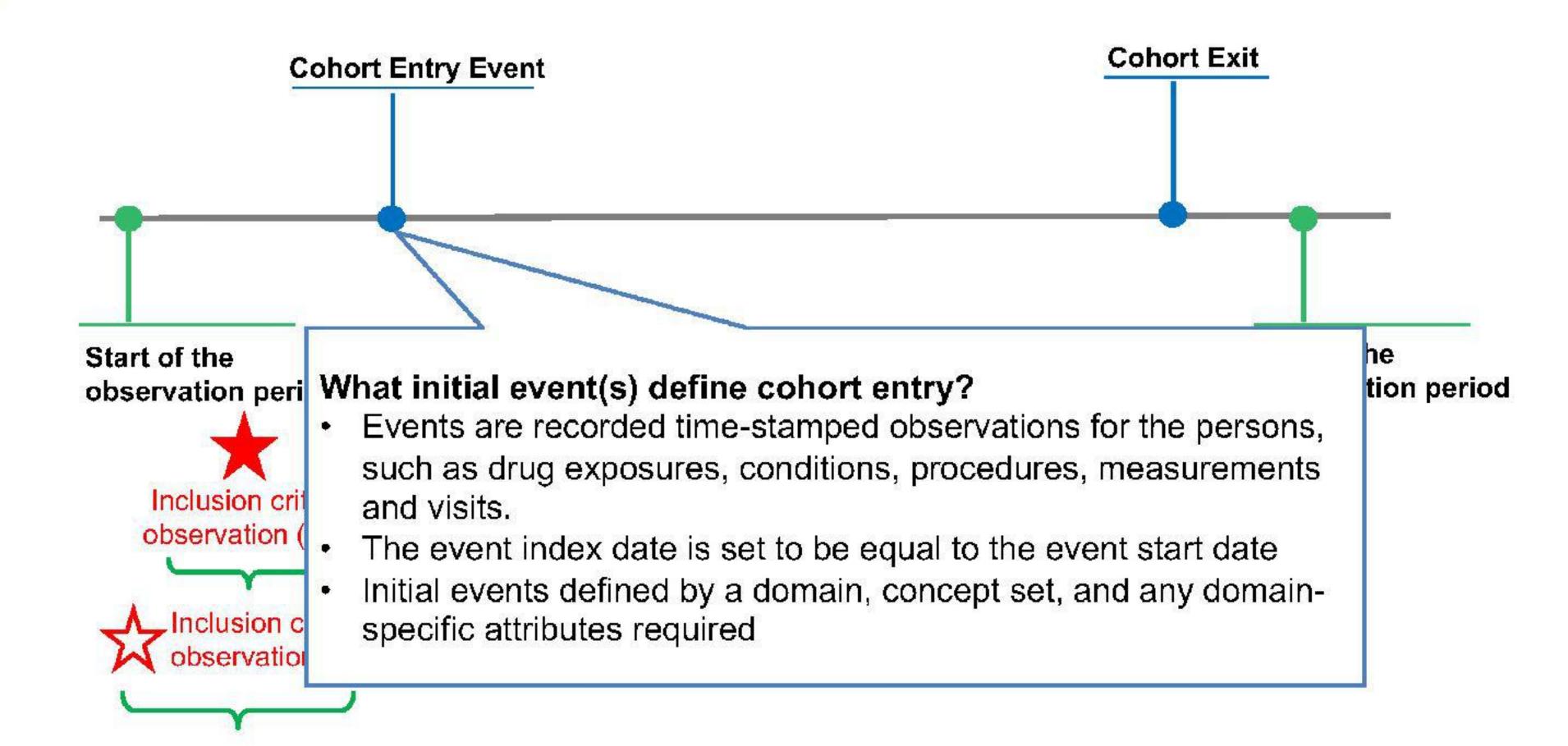


### The Anatomy of a Cohort Definition



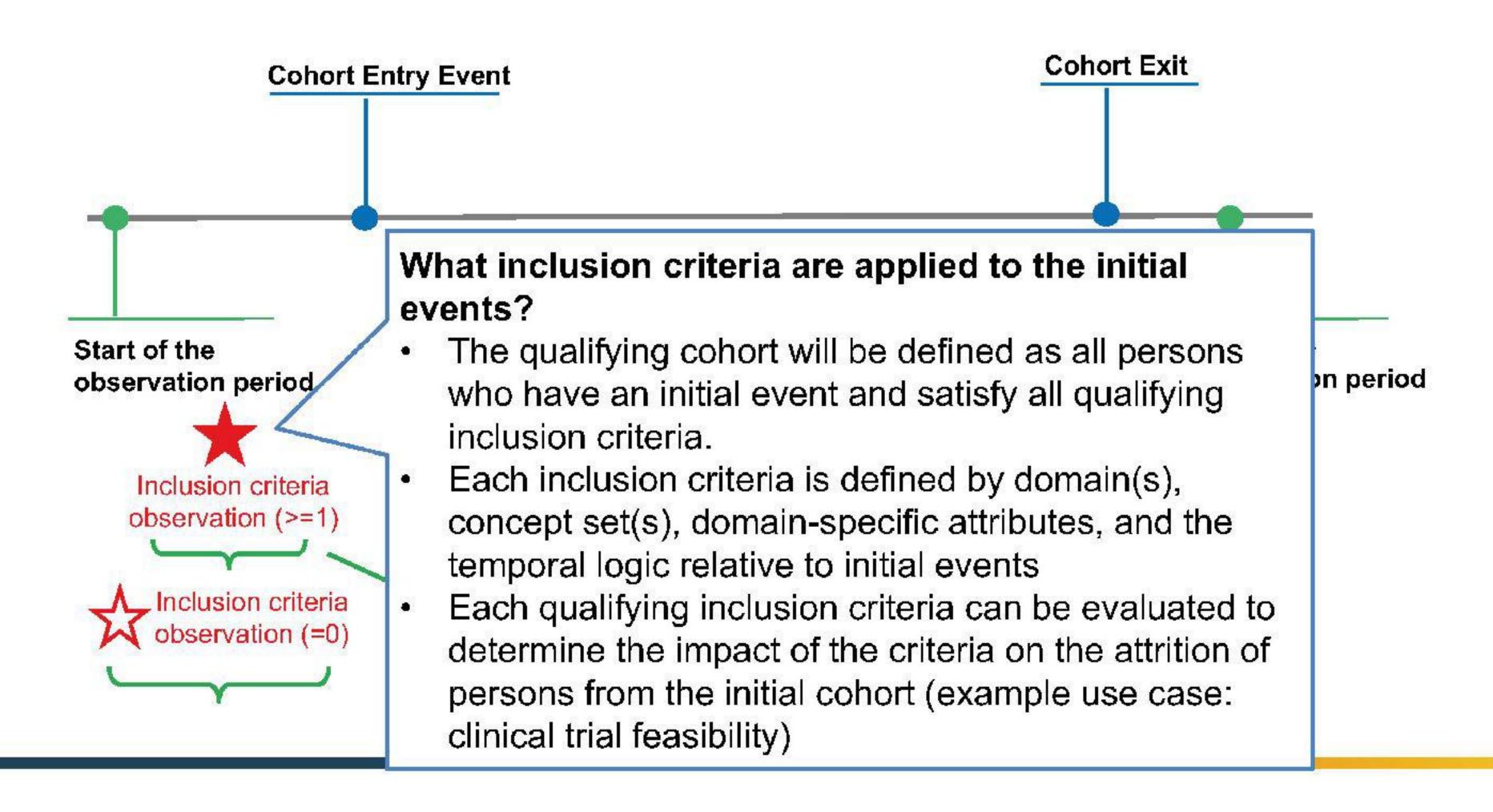


### The Anatomy of a Cohort Definition



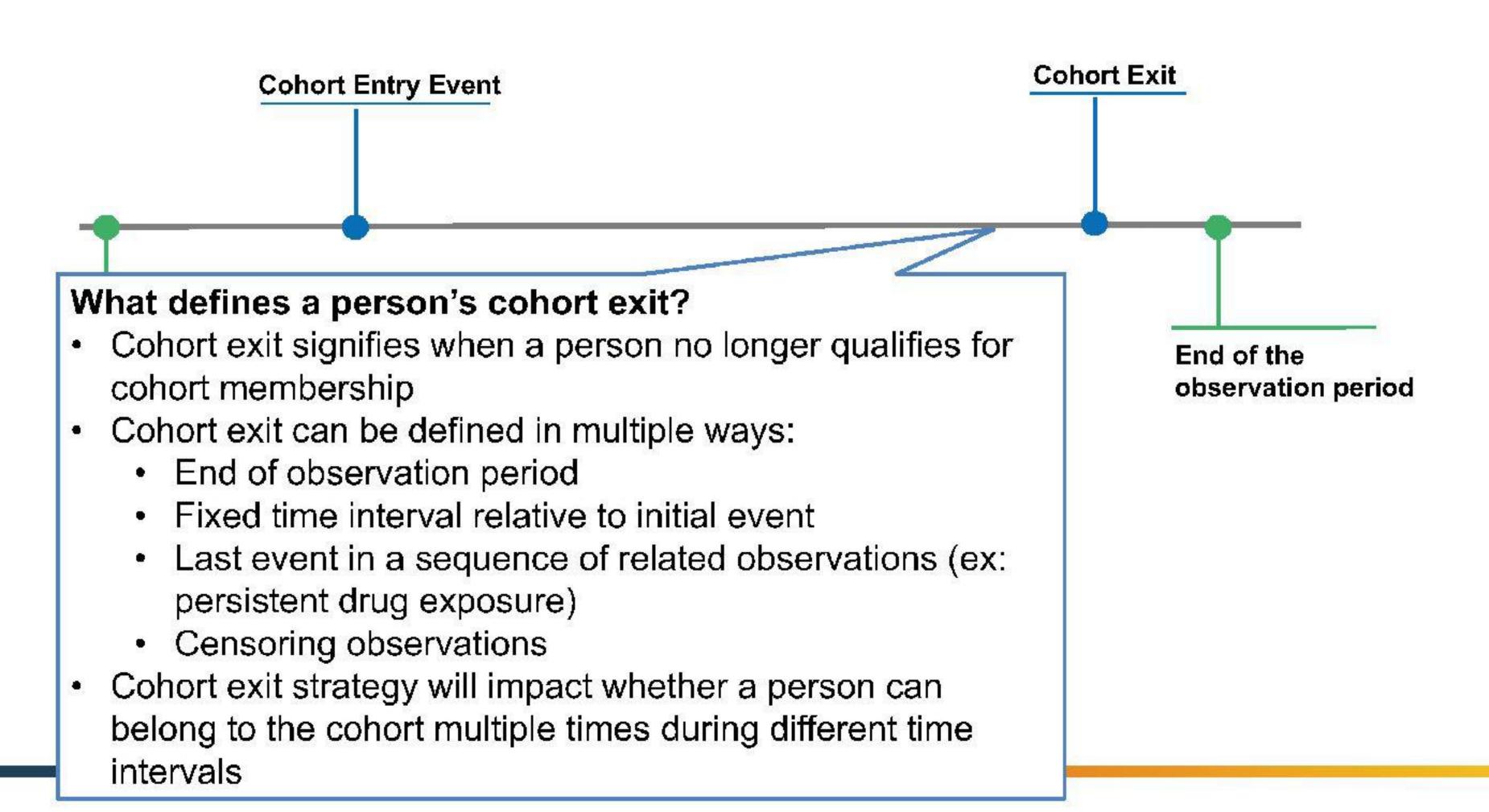


### The Anatomy of a Cohort Definition



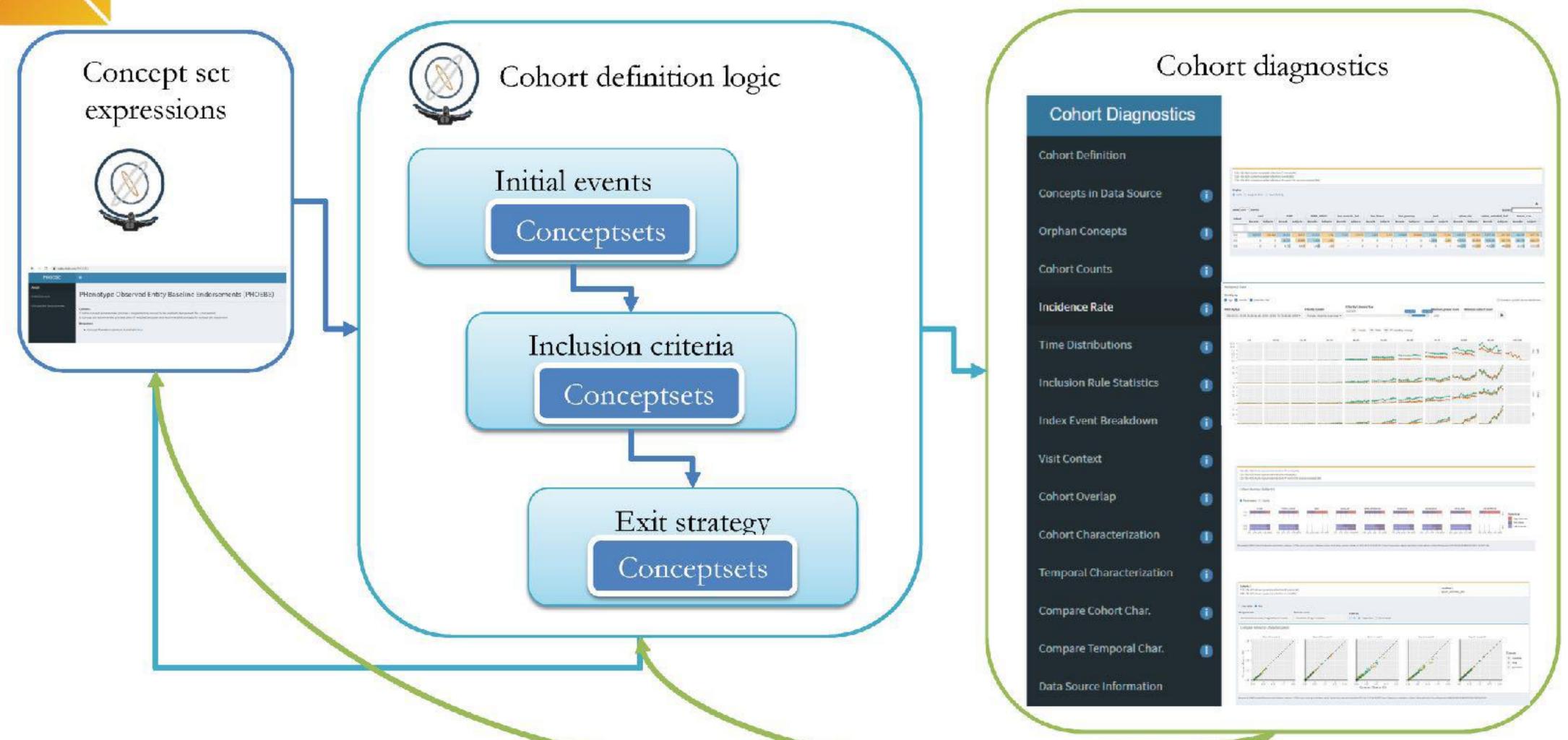


### The Anatomy of a Cohort Definition





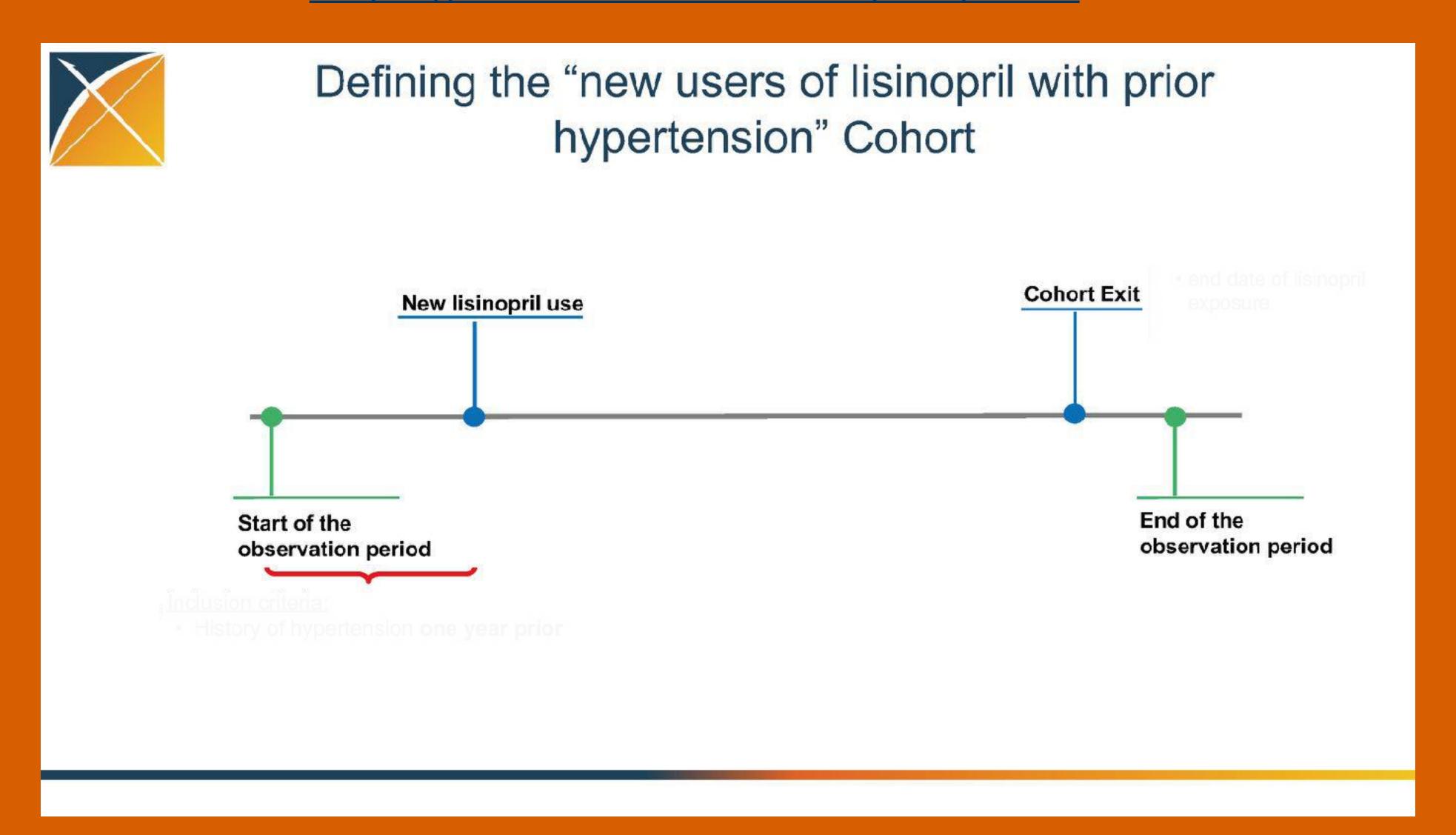
### Phenotype development and evaluation workflow



# Hands-on Practice: New Users of Lisinopril with prior Hypertension

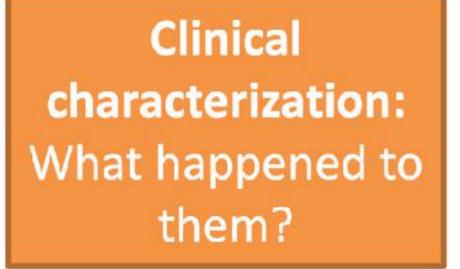


on slide & on Atlas: https://atlas-demo.sidata.plus/atlas





# Complementary evidence to inform the patient journey





observation



Patient-level
prediction:
What will happen
to me?



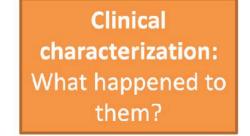
Population-level effect estimation:
What are the causal effects?

inference

causal inference



### Questions asked across the patient journey

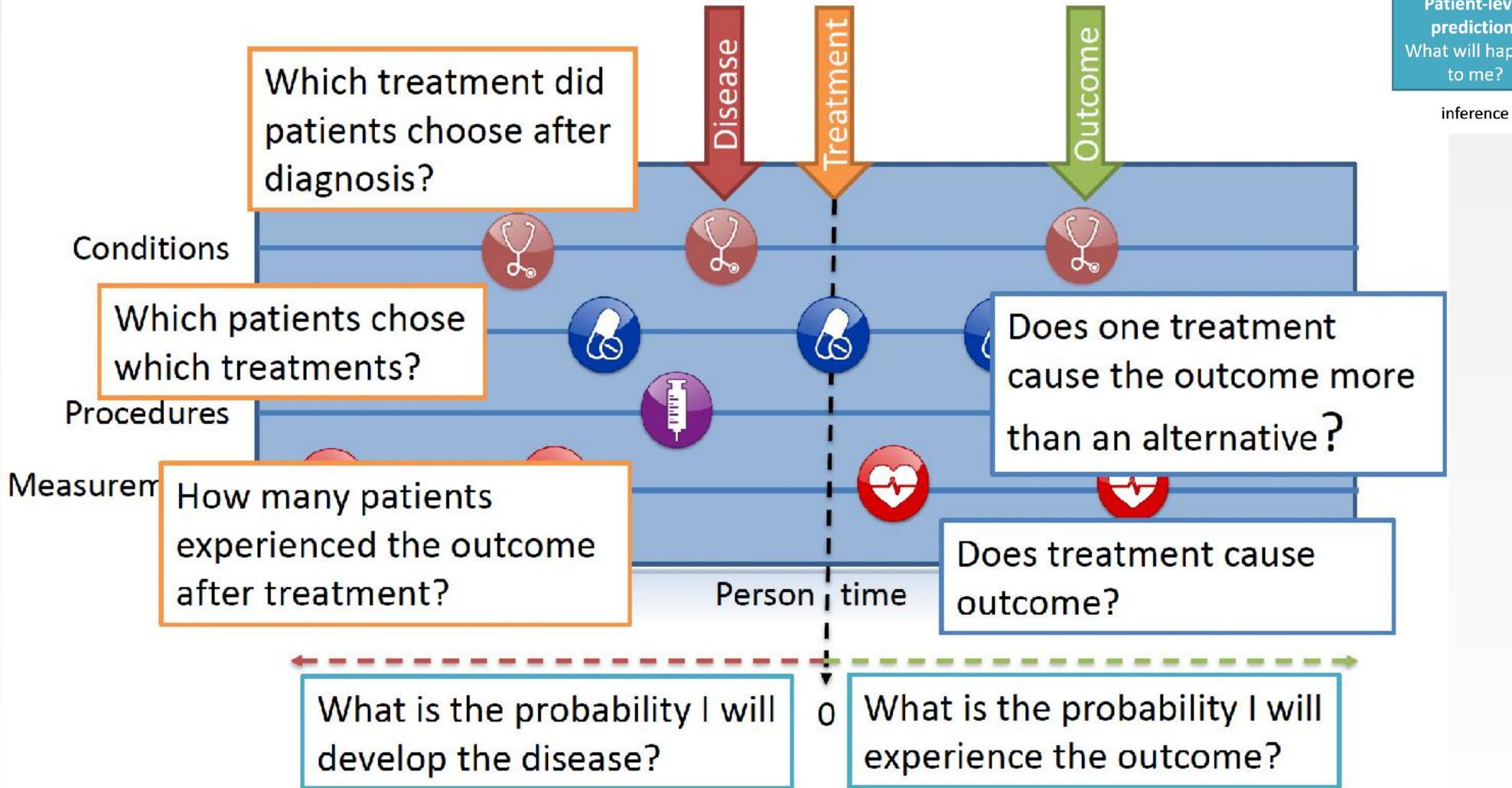


observation

**Patient-level** prediction: What will happen to me?

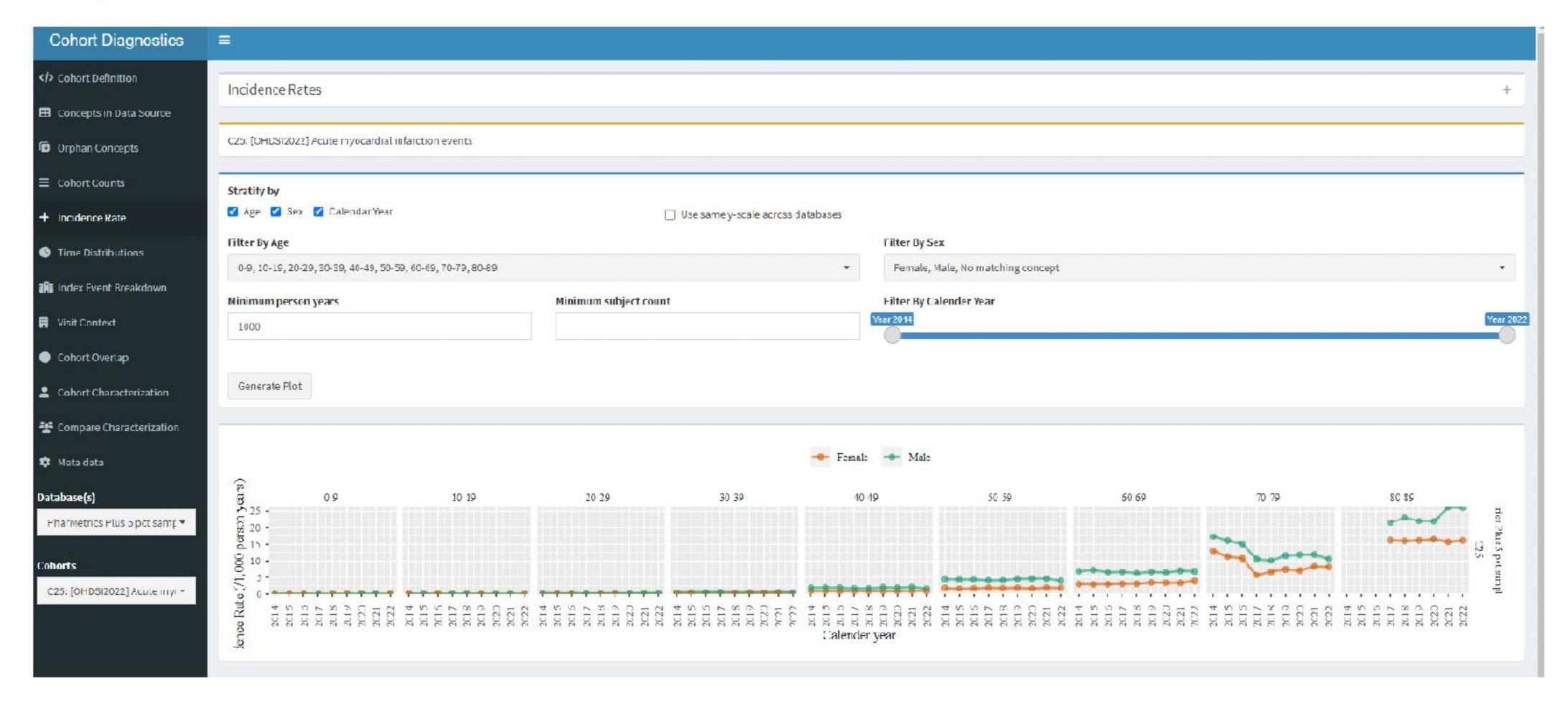
**Population-level** effect estimation: What are the causal effects?

causal inference



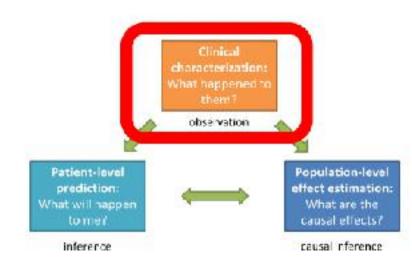


### Cohort Diagnostics – Incidence Rate





# OHDSI Characterization Framework



- Target cohort: who do you want to study?
- Stratification (pre-index): what subgroups do you want to study?
- Features of interest: what attributes do you want to look at and describe differences in?
- Time-at-risk: what windows of time do you want to describe features in?



## OHDSI in action: Clinical characterization



## Characterizing treatment pathways at scale using the OHDSI network

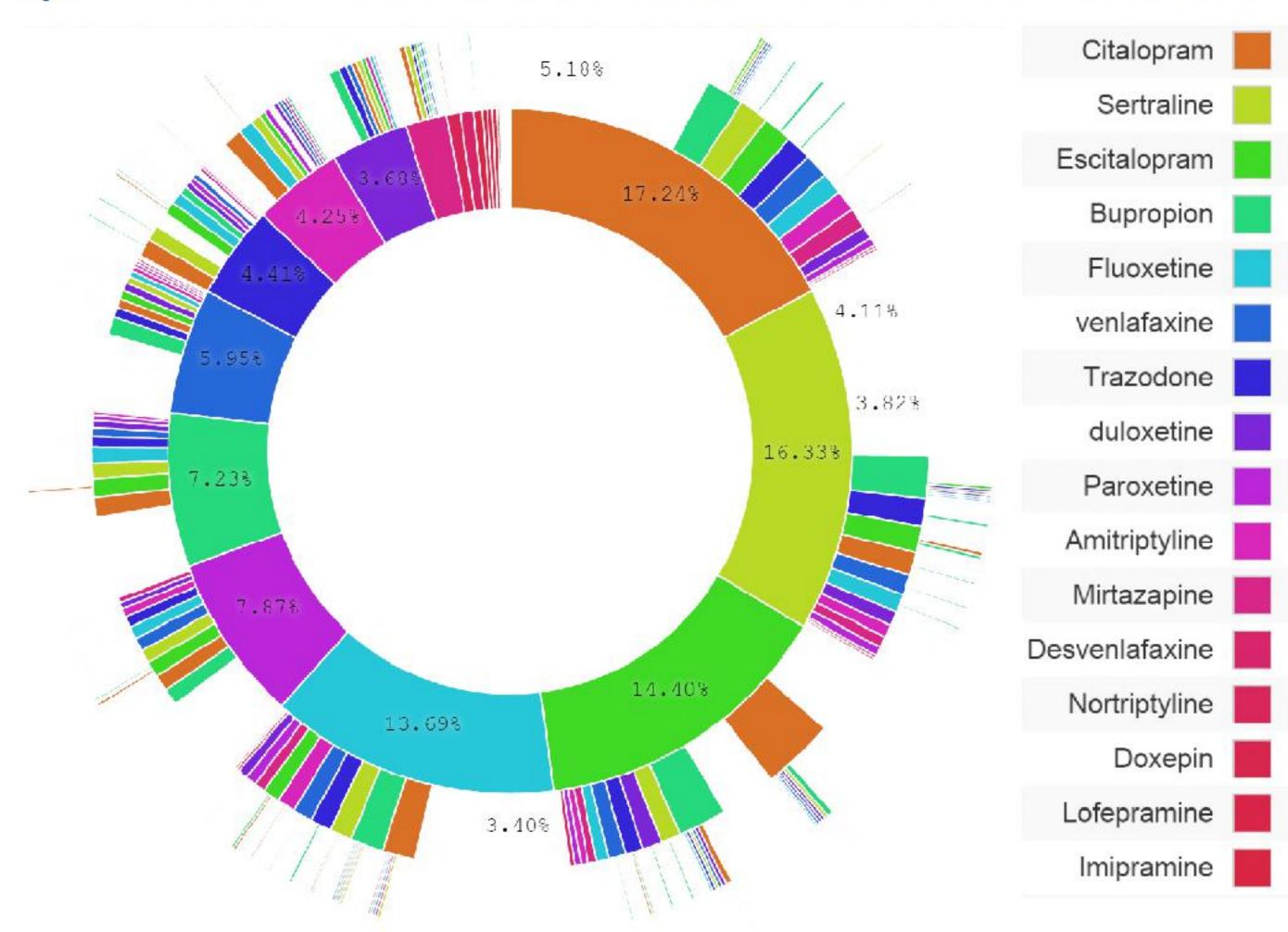
George Hripcsak<sup>a,b,c,1</sup>, Patrick B. Ryan<sup>c,d</sup>, Jon D. Duke<sup>c,e</sup>, Nigam H. Shah<sup>c,f</sup>, Rae Woong Park<sup>c,g</sup>, Vojtech Huser<sup>c,h</sup>, Marc A. Suchard<sup>c,i,j,k</sup>, Martijn J. Schuemie<sup>c,d</sup>, Frank J. DeFalco<sup>c,d</sup>, Adler Perotte<sup>a,c</sup>, Juan M. Banda<sup>c,f</sup>, Christian G. Reich<sup>c,l</sup>, Lisa M. Schilling<sup>c,m</sup>, Michael E. Matheny<sup>c,n,o</sup>, Daniella Meeker<sup>c,p,q</sup>, Nicole Pratt<sup>c,r</sup>, and David Madigan<sup>c,s</sup>

<sup>a</sup>Department of Biomedical Informatics, Columbia University Medical Center, New York, NY 10032; <sup>b</sup>Medical Informatics Services, NewYork-Presbyterian Hospital, New York, NY 10032; <sup>c</sup>Observational Health Data Sciences and Informatics, New York, NY 10032; <sup>d</sup>Epidemiology Analytics, Janssen Research and Development, Titusville, NJ 08560; <sup>c</sup>Center for Biomedical Informatics, Regenstrief Institute, Indianapolis, IN 46205; <sup>f</sup>Center for Biomedical Informatics Research, Stanford University, CA 94305; <sup>g</sup>Department of Biomedical Informatics, Ajou University School of Medicine, Suwon, South Korea, 443-380; <sup>h</sup>Lister Hill National Center for Biomedical Communications (National Library of Medicine), National Institutes of Health, Bethesda, MD 20894; <sup>h</sup>Department of Biomathematics, University of California, Los Angeles, CA 90095; <sup>h</sup>Department of Biostatistics, University of California, Los Angeles, CA 90095; <sup>h</sup>Department of Biomedical Informatics, University of Colorado School of Medicine, Aurora, CO 80045; <sup>n</sup>Department of Biomedical Informatics, Vanderbilt University Medical Center, Nashville, TN 37212; <sup>o</sup>Geriatric Research, Education and Clinical Center, VA Tennessee Valley Healthcare System, Nashville, TN 37212; <sup>p</sup>Department of Preventive Medicine, University of Southern California, Los Angeles, CA 90089; <sup>f</sup>Division of Health Sciences, University of South Australia, Adelaide, SA, Australia 5001; and <sup>s</sup>Department of Statistics, Columbia University, New York, NY 10027

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

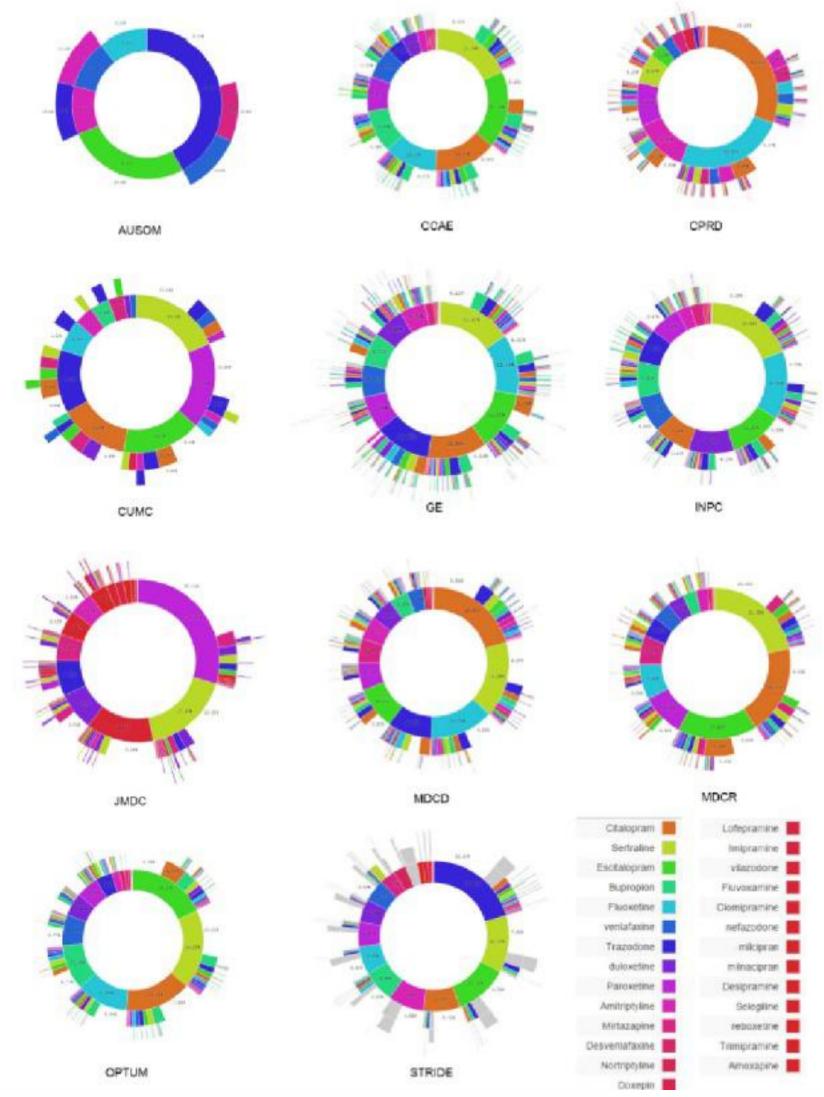


# How are patients with major depressive disorder *ACTUALLY* treated?





# How are patients with major depressive disorder *ACTUALLY* treated?



- Substantial variation in treatment practice across data sources, health systems, geographies, and over time
- Consistent heterogeneity in treatment choice as no source showed one preferred first-line treatment
- 11% of depressed patients followed a treatment pathway that was shared with no one else in any of the databases

Hripcsak et al, PNAS, 2016



# Hands-on: Characterization of Lisinopril users on Atlas <a href="https://atlas-demo.sidata.plus/atlas">https://atlas-demo.sidata.plus/atlas</a>

ATLAS	English V 🐥 I 😃								
☆ Home		on #2							
■ Data Sources	created by username1 on 2023-09-18 10:25								
Q Search	Lisinopril users-all analyses								
Concept Sets	Design Conce	ept Sets Executions Utilities Versions Messages							
Cohort Definitions	Enter the characterize	ation description here							
			ve summary statistics from person level covariate data. Summary st variates during a period may be stratified into temporal units of time						
	Billian Stranger Branch Stranger Branch	실망했다 이렇게 하게 아이들의 그렇게 하는 얼마를 하는데 있다면서 하는데 이렇게 아르아 아이를 하는데 하는데 하는데 아이를 하는데 하는데 하는데 하는데 하는데 아이들이 살았다.	in absolute calendar intervals such as calendar-week, calendar-mont						
🚓 Cohort Pathways	Cohort definition	on							
7 Incidence Rates	Import								
Profiles	Show 10 V entries			Filt	er: Search				
₫ <u>¢</u> Estimation	ld 🔺	Name			4	- ÷			
Prediction	4	new users of lisinopril with prior hypertension		Edit cohort	Remo	ive			
🖧 Reusables	Showing 1 to 1 of 1 ent	tries			Pre	evious 1 Next			
≆≣ Jobs	Feature analyse	es							
<b>♥</b> \$ Configuration	Import								
Feedback	Show 10 V entries			Filte	er: Search				
	ld 🌲	Name	Description		Action	ns 🍦			
Apache 2.0 open source software	1	Measurement Range Group Short Term	Covariates indicating whether measurements are below, within, or above no short term window.	rmal range in the	Remo	ve			
provided by  OHDSI	2	Condition Group Era Start Long Term	One covariate per condition era rolled up to groups in the condition_era table term window.	e starting in the long	g Remo	ve			
j <u>oin the journey</u> 3 Drug Group Era Start Medium Term  One covariate per drug rolled up to ATC groups in the drug era table starting in						ve			







## OHDSI Tools: Patient-level Prediction









### Session Overview

OHDSI Tools: Patient-level Prediction @ 14:45 – 15:45 (60 min)

Why? Background & Questions	How? Methods & Materials	What? Objectives
☐ How can we make a prediction at patient-level?	Introduce types of predictive models	★ Understand different types of prediction models
	OHDSI tools for patient-level prediction	★ Acquire hands-on experience in developing a predictive
	Hands-on: Develop a simple prediction model in Atlas	model using Atlas
	Most of slides from OHDSI2022 Tutorial session 7: <a href="https://www.ohdsi.org/ohdsi2022-tutorial/">https://www.ohdsi.org/ohdsi2022-tutorial/</a>	



# Complementary evidence to inform the patient journey





observation



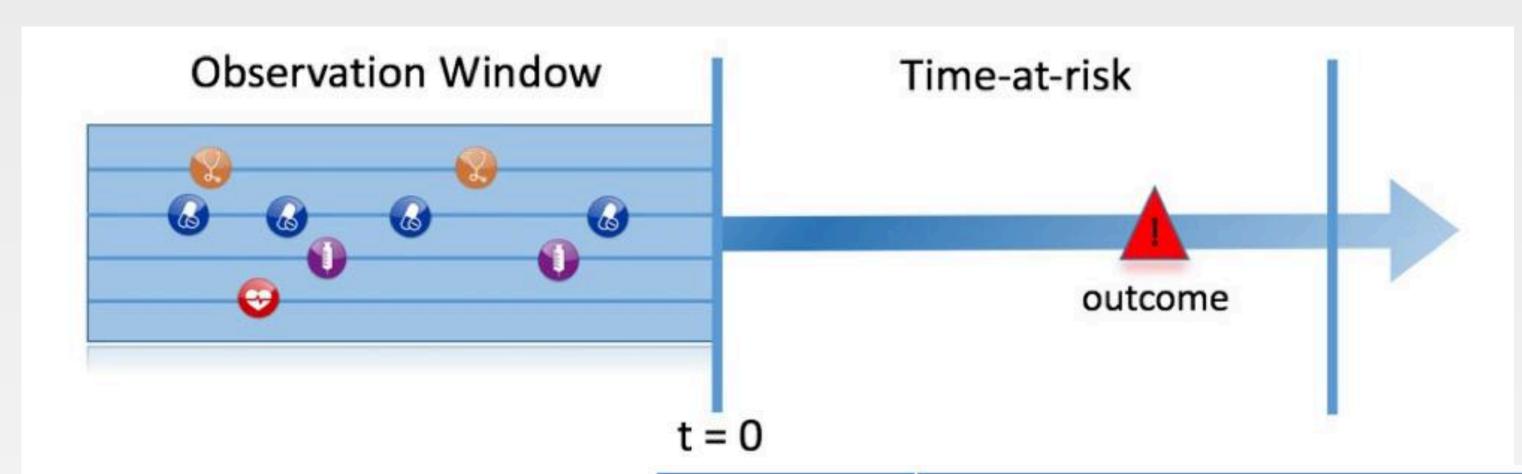
Patient-level
prediction:
What will happen
to me?



Population-level effect estimation:
What are the causal effects?

inference

causal inference





Туре	Structure	Example
Disease onset and progression	Amongst patients who are newly diagnosed with <insert disease="" favorite="" your="">, which patients will go on to have <another complication="" disease="" or="" related=""> within <time diagnosis="" from="" horizon="">?</time></another></insert>	Among newly diagnosed AFib patients, which will go onto to have ischemic stroke in next 3 years?
Treatment choice	Amongst patients with <indicated disease=""> who are treated with either <treatment 1=""> or <treatment 2="">, which patients were treated with <treatment 1=""> (on day 0)?</treatment></treatment></treatment></indicated>	Among AFib patients who took either warfarin or rivaroxaban, which patients got warfarin? (as defined for propensity score model)
Treatment response	Amongst patients who are new users of <insert chronically-used="" drug="" favorite="" your="">, which patients will <insert desired="" effect=""> in <time window="">?</time></insert></insert>	Which patients with T2DM who start on metformin stay on metformin after 3 years?
Treatment safety	Amongst patients who are new users of <insert drug="" favorite="" your="">, which patients will experience <insert adverse="" drug="" event="" favorite="" from="" known="" profile="" the="" your=""> within <time exposure="" following="" horizon="" start="">?</time></insert></insert>	Among new users of warfarin, which patients will have GI bleed in 1 year?
Treatment adherence	Amongst patients who are new users of <insert chronically-used="" drug="" favorite="" your="">, which patients will achieve <adherence metric="" threshold=""> at <time horizon="">?</time></adherence></insert>	Which patients with T2DM who start on metformin achieve >=80% proportion of days covered at 1 year?



## Prediction task specification

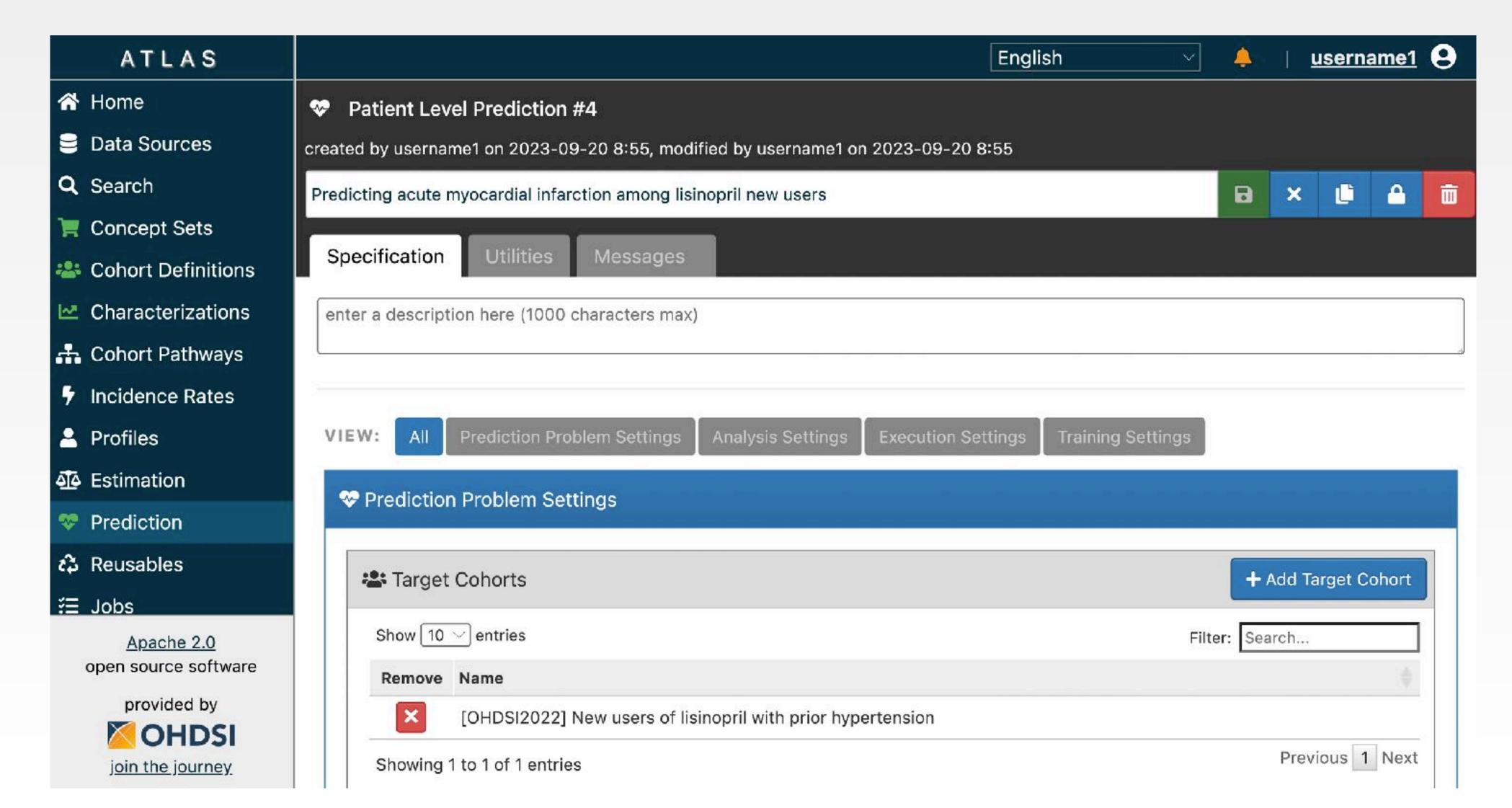
Component	Description
Target population (T):	Who do you want to do the prediction for?
Outcome (O):	What are you predicting?
Time-at-risk (TAR):	When are you predicting?





### Demo: Patient-level Prediction

Predicting acute myocardial infarction among lisinopril new users



#### Best Practice Research

Jenna Reps, Peter R. Rijnbeek

2023-08-28

Source: vignettes/BestPractices.rmd

## Best practice publications using the OHDSI PatientLevelPrediction framework

Topic	Research Summary	Link
Problem Specification	When is prediction suitable in observational data?	Guidelines needed
Data Creation	Comparison of cohort vs case-control design	Journal of Big Data
Data Creation	Addressing loss to follow-up (right censoring)	BMC medical informatics and decision makingk
Data Creation	Investigating how to address left censoring in features construction	BMC Medical Research Methodology
Data Creation	Impact of over/under-sampling	Study being developed
Data Creation	Impact of phenotypes	Study Done - Paper submitted
Model development	How much data do we need for prediction - Learning curves at scale	Preprint link
Model development	What impact does test/train/validation design have on model performance	BMJ Open
Model development	What is the impact of the classifier	JAMIA

#### Contents

Best practice publications using the OHDSI PatientLevelPrediction framework









## Data Governance for Research









### Session Overview

Data Governance for Research @ 15:45 – 16:15 (30 min)

Why? Background & Questions	How? Methods & Materials	What? Objectives
<ul> <li>□ What are the ethical considerations for data in healthcare?</li> <li>□ How does governance impact data quality and research integrity?</li> </ul>	<ul> <li>Principles of Data Governance</li> <li>OMOP/OHDSI compliant governance practices</li> </ul>	<ul> <li>★ Comprehend the criticality of data governance in healthcare research</li> <li>★ Understand how OMOP/OHDSI complies with data governance norms</li> </ul>

## Data Governance

### Promotion

Support and Enhance
Data Uses



## Regulation

Govern and Take Care of Data Uses

What are the data we have?

Where are the data?

How are the data collected and used?

Whose data is it?

How can we improve data quality?

How can we make the data more valuable?

#### Deliverables

Policies, Procedures,
Data Catalog,
Metadata,
Data Lineage,
Data Quality Assurance

How can we use the data given legal regulations & ethics guidelines?

How can we facilitate external parties' usage of our data assets given intellectual property & legal considerations?

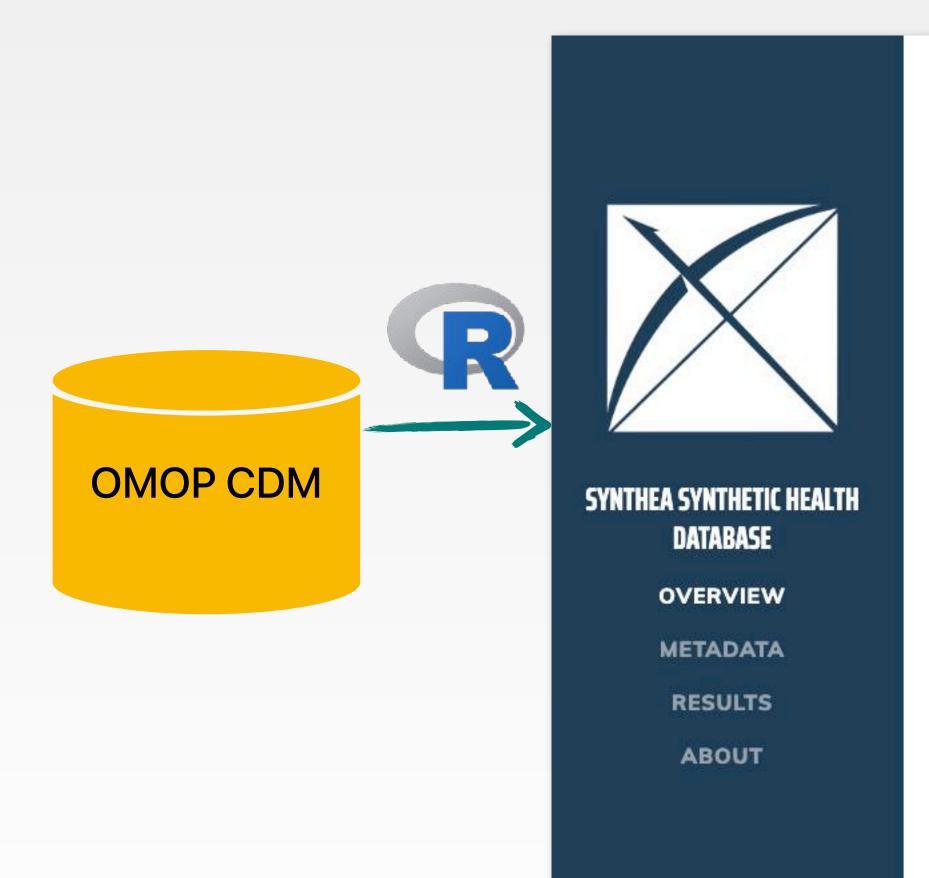


2 Prongs



## OHDSI Data Quality Dashboard

https://ohdsi.github.io/DataQualityDashboard/



#### DATA QUALITY ASSESSMENT

#### SYNTHEA SYNTHETIC HEALTH DATABASE

DataQualityDashboard Version: 2.0.0.100
Results generated at 2022-10-12 10:45:28 in 15 mins

	Verification					Validation			Total			
	Pass	Fail	Total	% Pass	Pass	Fail	Total	% Pass	Pass	Fail	Total	% Pass
Plausibility	2179	36	2215	98%	287	0	287	100%	2466	36	2502	99%
Conformance	996	11	1007	99%	180	0	180	100%	1176	11	1187	99%
Completeness	415	33	448	93%	12	4	16	75%	427	37	464	92%
Total	3590	80	3670	98%	479	4	483	99%	4069	84	4153	98%

2752 out of 4069 passed checks are Not Applicable, due to empty tables or fields.

1 out of 84 failed checks are SQL errors.

Corrected pass percentage for NA and Errors: 94% (1317/1400).







#### A Harmonized Data Quality Assessment Terminology and Framework for the Secondary Use of Electronic Health Record Data

Michael G. Kahn, MD, PhD;<sup>1</sup> Tiffany J. Callahan, MPH;<sup>1</sup> Juliana Barnard, MA;<sup>1</sup> Alan E. Bauck;<sup>11</sup> Jeff Brown, PhD;<sup>11</sup> Bruce N. Davidson, PhD;<sup>14</sup> Hossein Estiri, PhD;<sup>14</sup> Carsten Goerg, PhD;<sup>1</sup> Erin Holve, PhD, MPH, MPP;<sup>14</sup> Steven G. Johnson, MS;<sup>14</sup> Siaw-Teng Liaw, MBBS, PhD, FRACGP, FACHI;<sup>14</sup> Marianne Hamilton-Lopez, PhD, MPA;<sup>14</sup> Daniella Meeker, PhD;<sup>15</sup> Toan C. Ong, PhD;<sup>16</sup> Patrick Ryan, PhD;<sup>16</sup> Ning Shang, PhD;<sup>16</sup> Nicole G. Weiskopf, PhD;<sup>17</sup> Chunhua Weng, PhD, FACMI;<sup>17</sup> Meredith N. Zozus, PhD;<sup>17</sup> Lisa Schilling, MD<sup>17</sup>

#### **ABSTRACT**

**Objective:** Harmonized data quality (DQ) assessment terms, methods, and reporting practices can establish a common understanding of the strengths and limitations of electronic health record (EHR) data for operational analytics, quality improvement, and research. Existing published DQ terms were harmonized to a comprehensive unified terminology with definitions and examples and organized into a conceptual framework to support a common approach to defining whether EHR data is 'fit' for specific uses.



Table 1. Harmonized DQ Terms, Definitions, and Examples: Organized by Verification and Validation Contexts Within Categories and Subcategories

VER	FICATION	VALIDATION		
DEFINITION	EXAMPLE	DEFINITION	EXAMPLE	
CONFORMANCE	E: DO DATA VALUES ADHERE	TO SPECIFIED STANDARDS AN	ND FORMATS?	
	VALUE CONF	ORMANCE		
a. Data values conform to internal formatting constraints.	a. Sex is only one ASCII character.	<ul> <li>a. Data values conform to representational constraints based on external standards.</li> </ul>	a. Values for primary language conform to ISO standards.	
b. Data values conform to allowable values or ranges.	b. Sex only has values "M," "F," or "U."			
	RELATIONAL CO	NFORMANCE		
a. Data values conform to relational constraints.	a. Patient medical record number links to other tables as	a. Data values conform to relational constraints based on	a. Data values conform to all not-	
b. Unique (key) data values are not duplicated.	required.  b. A medical record number is assigned to a single patient.	external standards.	NULL requirements in a common multi- institutional data	
<ul> <li>c. Changes to the data model or data model versioning.</li> </ul>	c. Version 1 data does not include medical discharge hour.		exchange format.	
	COMPUTATIONAL	CONFORMANCE		
a. Computed values conform to computational or programming specifications.	a. Database- and hard- calculated Body Mass Index (BMI) values are identical.	<ul> <li>a. Computed results based on published algorithms yield values that match validation values provided by external source.</li> </ul>	<ul> <li>a. Computed BMI percentiles yield identical values compared to test results and values provided by the CDC.</li> </ul>	
	COMPLETENESS: ARE DA	TA VALUES PRESENT?		
a. The absence of data values at a single moment	a. The encounter ID variable has missing values.	a. The absence of data values at a single moment	a. The current encounter ID variable	
in time agrees with local or common expectations.	b. Gender should not be null.	in time agrees with trusted reference standards or	is missing twice as many values as the	
b. The absence of data	c. Medical discharge time is missing for three	external knowledge.	institutionally validated database.	
values measured over time agrees with local or common expectations.	consecutive days.	<ul> <li>b. The absence of data values measured over time agrees with trusted reference standards or external knowledge.</li> </ul>	<ul><li>b. A drop in ICD- 9CM codes matches implementation of ICD-10CM</li></ul>	
	PLAUSIBILITY: ARE DATA	VALUES BELIEVABLE?		
	UNIQUENESS P	LAUSIBILITY		
a. Data values that identify a single object are not duplicated.	<ul> <li>a. Patients from a single institution do not have multiple medical record numbers.</li> </ul>	<ul> <li>a. Data values that identify a single object in an external source are not duplicated.</li> </ul>	<ul> <li>a. An institution's CMS facility identifier does not refer to a multiple institutions.</li> </ul>	

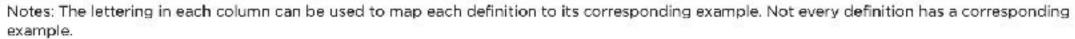






Table 1. Harmonized DQ Terms, Definitions, and Examples: Organized by Verification and Validation Contexts Within Categories and Subcategories (Cont'd)

VER	IFICATION	VALIDATION			
DEFINITION	EXAMPLE	DEFINITION	EXAMPLE		
	ATEMPORAL P	LAUSIBILITY			
istributions agree with an internal measurement or ocal knowledge.  Data values and distributions or independent neasurements of the same fact are in greement.  Logical constraints between values agree with local or common nowledge (includes expected" missingness).  Values of repeated neasurement of the arma fact show expected ariability.	a. Height and weight values are positive.  a. Counts of unique patients by diagnoses are as expected  a. Distribution of encounters per patient or medications per encounter distributions are as expected  b. Serum glucose measurement is similar to finger stick glucose measurement.  b. Oral and axillary temperatures are similar.  c. Sex values agree with sexspecific contexts (pregnancy, prostate cancer).  d. Height values are similar when taken by two separate nurses within the same facility using the same equipment.	a. Data values and distributions (including subgroup distributions) agree with trusted reference standards or external knowledge.  b. Similar values for identical measurements are obtained from two independent databases representing the same observations with equal credibility.  c. Two dependent databases (e.g., database 1 abstracted from database 2) yield similar values for identical variables.	a. HbA1c values from hospital and national reference lab are statistically similar under the same conditions.  a. Distribution of patients with cardiovascular disease diagnoses are similar to CDC rates for the same age and sex groups  a. Readmission rates by age groups for Medicare patients agree with CMS values  b. Diabetes ICD-9CM and CPT codes are similar between two independent claims databases serving similar populations.  c. Recorded date of birth is consistent between EHR data and registry data for the same patient.		
	TEMPORAL PI	AUSIBILITY			
Disperved or derived alues conform to expected temporal properties.  Sequences of values that represent state ransitions conform to expected properties.  Measures of data value lensity against a time-priented denominator are expected based on internal knowledge.	<ul> <li>a. Admission date occurs before discharge date.</li> <li>b. Date of an initial immunization precedes date of a booster immunization.</li> <li>c. Similar counts of patient observations between extraction-transformation-load cycles.</li> <li>c. Counts of emergency room visits by month shows expected spike during flu season.</li> <li>c. Medications per patient-day are as expected</li> </ul>	<ul> <li>a. Observed or derived values have similar temporal properties across one or more external comparators or gold standards.</li> <li>b. Sequences of values that represent state transitions are similar to external comparators or gold standards.</li> <li>c. Measures of data value density against a time-oriented denominator are expected based on external knowledge.</li> </ul>	a. Length of stay by outpatient procedure types conforms to Medicare data for similar populations. b. Immunization sequences match the CDC recommendations c. Counts of emergency room visits by month shows spike during flu season that are similar to local health department reports. c. Medications per patient-day matches claims data.		



Extract, Transform, Load ETL (ETL); International Organization for Standardization (ISO); Electronic Health Record (EHR) Data; International Classification of Diseases, Ninth and Tenth Revisions (ICD-9CM and ICD-IOCM); Current Procedural Terminology (CPT); Centers for Medicare & Medicaid Services (CMS); Centers for Disease Control and Prevention (CDC).

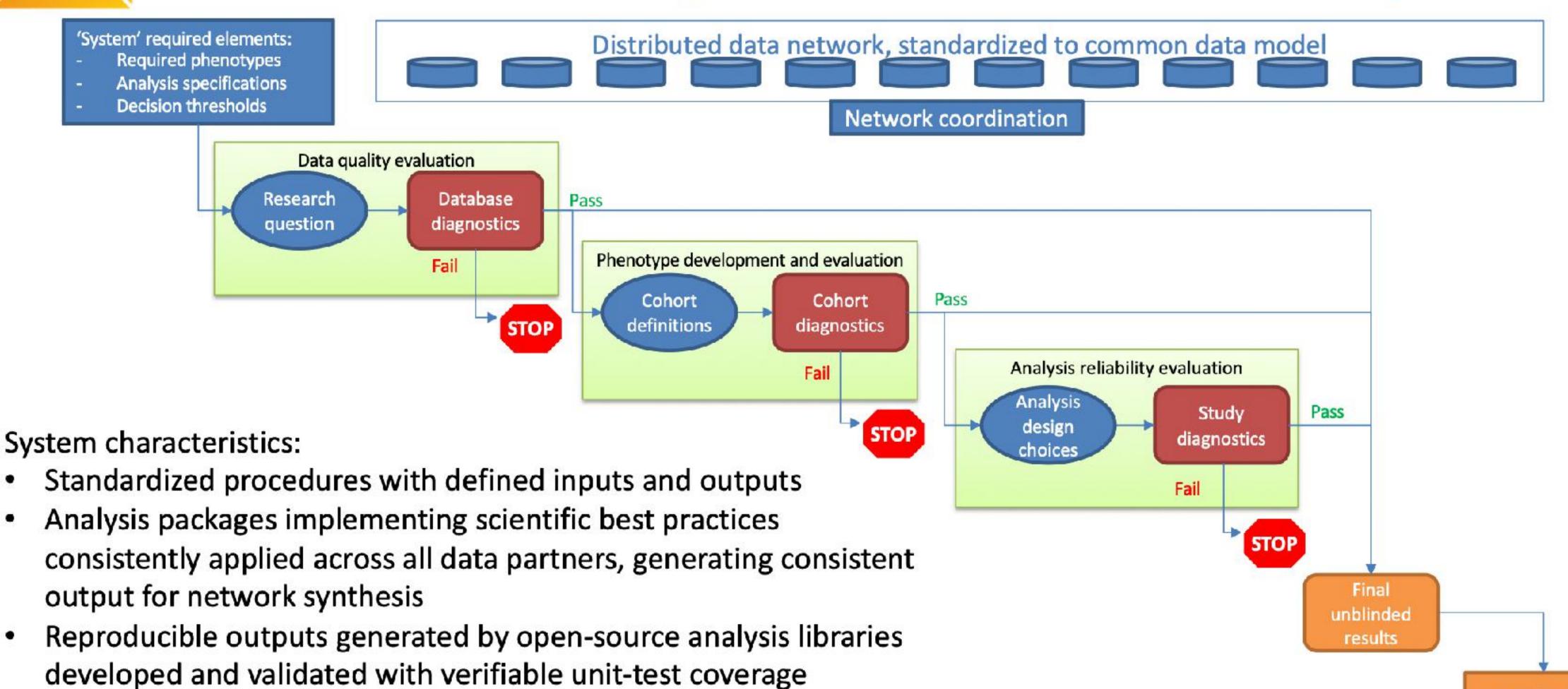








# Engineering open science systems that build trust into the real-world evidence generation and dissemination process



from 11Jan2022 OHDSI ca

Interface for

exploration

Measurable operating characteristics of system performance

Pre-specified and objective decision thresholds for go/no go criteria



## Secondary Use of Health Data

European review by Open Data Institute





## Secondary Use of Health Data

### National example from UK

ในสหราชอาณาจักร เมื่อปี 2022 กระทรวง Health and Social Care ได้จัด ทำการศึกษาและสรุปคำแนะนำการ ใช้ข้อมูลสุขภาพเพื่อการวิเคราะห์และวิจัย ในสหราชอาณาจักร ชื่อว่า "Better, broader, safer: using health data for research and analysis" หรือเรียกอย่างไม่เป็นทางการว่า Goldacre Review ตามชื่อของประธานคณะศึกษา Professor Ben Goldacre จากมหาวิทยาลัย Oxford โดยแบ่งคำแนะนำไว้เป็น 6 ด้าน

- 1. Platforms and security
- 2. Modern, open working methods for NHS data
- 3. Data curation and knowledge management
- 4. NHS data analysts
- 5. Governance
- 6. Approaches and strategy

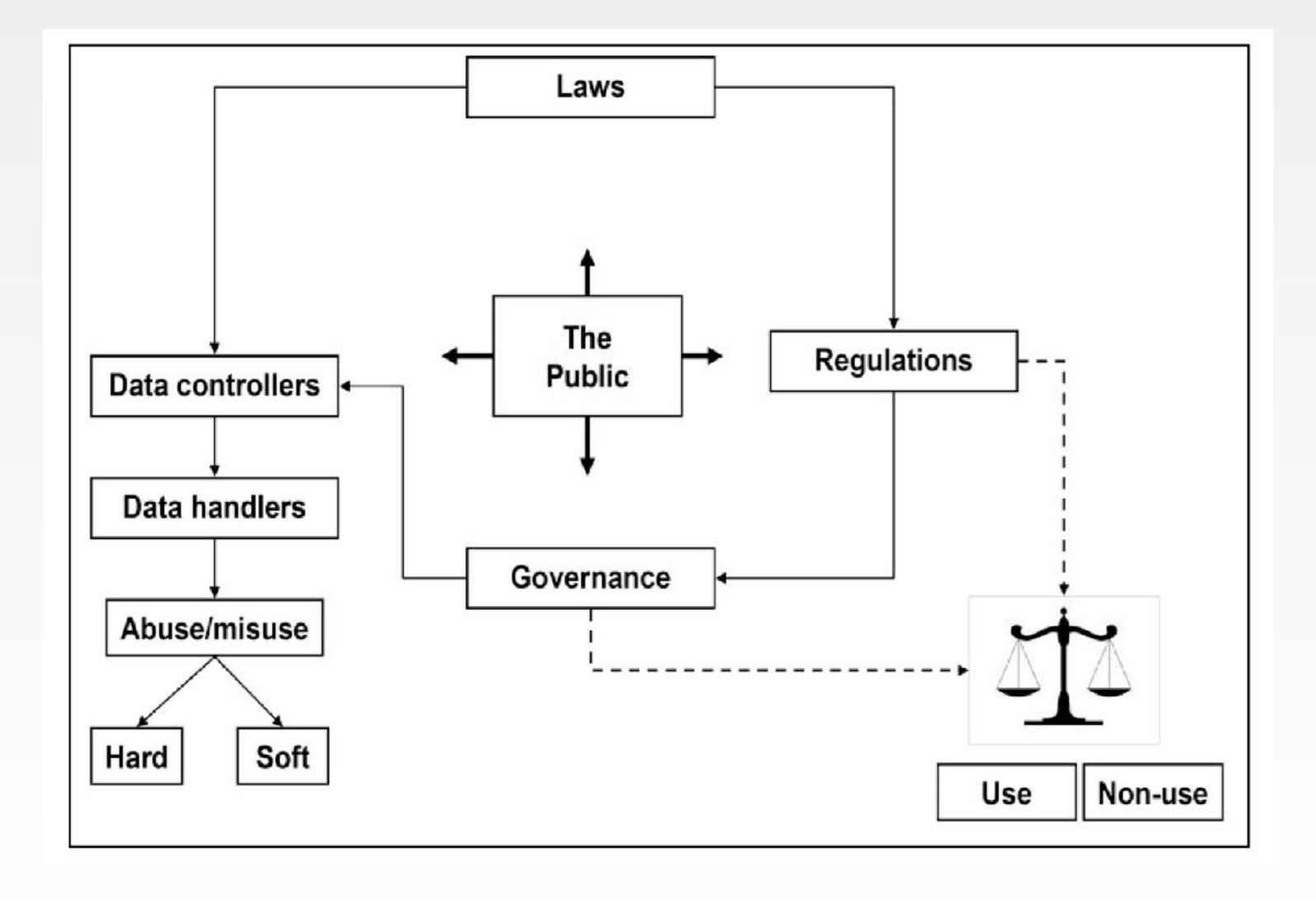








### Secondary Use of Health Data Governance



### Data Protection Measures



เล่ม ๑๓๙ ตอนพิเศษ ๑๔๐ ง ราชกิจจานุเบกษา

๒๐ มิถุนายน ๒๕๖๕

#### ประกาศคณะกรรมการคุ้มครองข้อมูลส่วนบุคคล

เรื่อง มาตรการรักษาความมั่นคงปลอดภัยของผู้ควบคุมข้อมูลส่วนบุคคล พ.ศ. ๒๕๖๕

- ข้อ ๔ ผู้ควบคุมข้อมูลส่วนบุคคลมีหน้าที่จัดให้มีมาตรการรักษาความมั่นคงปลอดภัย ที่เหมาะสม เพื่อป้องกันการสูญหาย เข้าถึง ใช้ เปลี่ยนแปลง แก้ไข หรือเปิดเผยข้อมูลส่วนบุคคล โดยปราศจากอำนาจหรือโดยมิชอบ โดยมาตรการรักษาความมั่นคงปลอดภัยดังกล่าว อย่างน้อยต้องมี การดำเนินการ ดังต่อไปนี้
- (๑) มาตรการรักษาความมั่นคงปลอดภัยดังกล่าว จะต้องครอบคลุมการเก็บรวบรวม ใช้ และเปิดเผยข้อมูลส่วนบุคคล ตามกฎหมายว่าด้วยการคุ้มครองข้อมูลส่วนบุคคล ไม่ว่าข้อมูลส่วนบุคคล ดังกล่าวจะอยู่ในรูปแบบเอกสารหรือในรูปแบบอิเล็กทรอนิกส์ หรือรูปแบบอื่นใดก็ตาม
- (๒) มาตรการรักษาความมั่นคงปลอดภัยดังกล่าว จะต้องประกอบด้วยมาตรการเชิงองค์กร (organizational measures) และมาตรการเชิงเทคนิค (technical measures) ที่เหมาะสม ซึ่งอาจ รวมถึงมาตรการทางกายภาพ (physical measures) ที่จำเป็นด้วย โดยคำนึงถึงระดับความเสี่ยง ตามลักษณะและวัตถุประสงค์ของการเก็บรวบรวม ใช้ และเปิดเผยข้อมูลส่วนบุคคล ตลอดจนโอกาสเกิด และผลกระทบจากเหตุการละเมิดข้อมูลส่วนบุคคล

#### 1. Organizational Measures, e.g.,

- 1.1. CIOMS Guideline 2016
- 1.2. Declaration of Taipei 2016
- 1.3. PDPA 2019
- 1.4. IRB

#### 2. Technical Measures, e.g.,

- 2.1. Shift and Truncate for De-identification
- 2.2. Secure Remote Research Environment
- 2.3. Conventional security settings



# THE COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (CIOMS) International Ethical Guidelines for Health-related Research Involving Humans (2016), GUIDELINE 12: COLLECTION, STORAGE AND USE OF DATA IN HEALTH-RELATED RESEARCH

	สิ่งที่ต้องกำหนดตาม Commentary Guideline 12	สรุปใจความสำคัญ
1	to which legal entity the material is entrusted	นิติบุคคลที่ได้รับมอบหมายให้จัดการข้อมูล
2	how authorization from the donor is obtained	วิธีการได้มาซึ่งการอนุญาตให้ใช้ข้อมูลจากผู้ให้ข้อมูล
3	how the donor can retract this authorization	วิธีการยกเลิกการอนุญาตโดยผู้ให้ข้อมูล
4	in which circumstances donors need to be recontacted	เมื่อเกิดเหตุการณ์ใดจึงจะต้องติดต่อผู้ให้ข้อมูล
5	a procedure for determining whether unsolicited findings should be disclosed, and if so, how they should be managed	กระบวนการพิจารณาว่าควรเปิดเผยผลการค้นพบที่ไม่ได้ ร้องขอหรือไม่ หากใช่ ควรจัดการอย่างไร
6	how the quality of the data collection is controlled	วิธีการควบคุมคุณภาพการเก็บรวบรวมข้อมูล
7	how confidentiality of the link between collected data and personal identifiers of the donors is maintained	วิธีการรักษาความลับระหว่างข้อมูลที่เก็บและตัวบ่งชี้ส่วนบุคคล ของผู้ให้ข้อมูล
8	who may have access to the data for future research, and under what circumstances	ใครสามารถเข้าถึงข้อมูลเพื่อการวิจัยในอนาคต และใน สถานการณ์ใด
9	which body may review research proposals for future use of the data	หน่วยงานใดสามารถตรวจสอบข้อเสนอการวิจัยสำหรับการใช้ ข้อมูลในอนาคต
10	appropriate mechanisms for keeping donors informed of research outcomes	กลไกที่เหมาะสมสำหรับการแจ้งให้ผู้ให้ข้อมูลทราบผลการวิจัย



# THE COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (CIOMS) International Ethical Guidelines for Health-related Research Involving Humans (2016), GUIDELINE 12: COLLECTION, STORAGE AND USE OF DATA IN HEALTH-RELATED RESEARCH

(cont'd)

	สิ่งที่ต้องกำหนดตาม Commentary Guideline 12	สรุปใจความสำคัญ
11	how participatory engagement with patient groups or the wider community is organized	วิธีการจัดการมีส่วนร่วมกับกลุ่มผู้ป่วยหรือสังคม
12	to which other sources of personal information the results of analyses with data may be linked	แหล่งข้อมูลส่วนบุคคลอื่นที่ผลการวิเคราะห์ด้วยข้อมูลอาจถูก เชื่อมโยง
13	in broad terms, which types of research will be pursued	ประเภทของการวิจัยที่จะมีการดำเนินการโดยคร่าว
14	which types of research will be excluded or included only after recontacting the donor for consent	ประเภทของการวิจัยที่จะต้องดำเนินการได้หลังจากติดต่อผู้ให้ ข้อมูลเพื่อขอความยินยอมแล้วเท่านั้น
15	to whom any benefits from the research are expected to accrue	ใครที่คาดหวังว่าจะได้รับประโยชน์จากการวิจัย
16	appropriate mechanisms for keeping participants informed of research outcomes	กลไกที่เหมาะสมสำหรับการแจ้งให้ผู้เข้าร่วมทราบผลการวิจัย
17	how the rights and welfare of individuals from whom the data were collected are not adversely affected	วิธีการที่สิทธิและสวัสดิภาพของบุคคลที่ข้อมูลถูกเก็บรวบรวม จะไม่ได้รับผลกระทบในทางลบ



## World Medical Association (WMA) DECLARATION OF TAIPEI ON ETHICAL CONSIDERATIONS REGARDING HEALTH DATABASES AND BIOBANKS (2016)



	Declaration of Taipei ช้อ 21	สรุปใจความสำคัญ
1	The purpose of the Health Database or Biobank	วัตถุประสงค์ของฐานข้อมูลสุขภาพหรือ Biobank
2	The nature of health data and biological material that will be contained in the Health Database or Biobank	ลักษณะของข้อมูลสุขภาพและวัตถุชีวภาพที่จะถูกจัดเก็บในฐานข้อมูล สุขภาพหรือ Biobank
3	Arrangements for the length of time for which the data or material will be stored	กำหนดระยะเวลาการจัดการเก็บข้อมูลหรือวัตถุ
4	Arrangements for regulations of the disposal and destruction of data or material	กำหนดระเบียบการทำลายข้อมูลหรือวัตถุ
5	Arrangement for how the data and material will be documented and traceable in accordance with the consent of the concerned persons	กำหนดการจัดการวิธีการบันทึกและติดตามข้อมูลและวัตถุตามความ ยินยอมของบุคคลที่เกี่ยวข้อง
6	Arrangement for how the data and material will be dealt with in the event of change of ownership or closure	กำหนดการจัดการวิธีการจัดการข้อมูลและวัตถุในกรณีที่มีการเปลี่ยน เจ้าของหรือปิดโครงการ
7	Arrangement for obtaining appropriate consent or other legal basis for data or material collection	กำหนดการจัดการในการขอความยินยอมที่เหมาะสมหรือฐาน กฎหมายอื่นสำหรับการเก็บข้อมูลหรือวัตถุ
8	Arrangements for protecting dignity, autonomy, privacy and preventing discrimination	กำหนดการจัดการในการปกป้องเกียรติยศ อิสรภาพ ความเป็นส่วน ตัว และป้องกันการเลือกปฏิบัติ
9	Criteria and procedures concerning the access to and the sharing of the health data or biological material including the systematic use of Material Transfer Agreement (MTA) when necessary	เกณฑ์และขั้นตอนเกี่ยวกับการเข้าถึงและการแบ่งปันข้อมูลสุขภาพ หรือวัตถุชีวภาพ รวมถึงระบบการใช้ Material Transfer Agreement (MTA) เมื่อจำเป็น

10	The person or persons who are responsible for the governance	บุคคลหรือผู้ที่รับผิดชอบในการจัดการธรรมาภิบาล
11	The security measures to prevent unauthorized access or inappropriate sharing	มาตรการรักษาความปลอดภัยเพื่อป้องกันการเข้าถึงโดยไม่ได้รับ อนุญาตหรือการแบ่งปันที่ไม่เหมาะสม
12	The procedures for re-contacting participants where relevant	ชั้นตอนสำหรับการติดต่อผู้เข้าร่วมซ้ำในที่เกี่ยวข้อง
13	The procedures for receiving and addressing enquiries and complaints	ขั้นตอนสำหรับรับและจัดการคำปรึกษาและข้อร้องเรียน



## พระราชบัญญัติสุขภาพแห่งชาติ พ.ศ. 2550

มาตรา 7 ข้อมูลด้านสุขภาพของบุคคล เป็นความลับส่วนบุคคล ผู้ใดจะนำไปเปิดเผยในประการที่น่าจะทำให้ บุคคลนั้นเสียหายไม่ได้ เว้นแต่การเปิดเผยนั้นเป็นไปตามความประสงค์ของบุคคลนั้นโดยตรง หรือมี กฎหมายเฉพาะบัญญัติให้ต้องเปิดเผย แต่ไม่ว่าในกรณีใด ๆ ผู้ใดจะอาศัยอำนาจหรือสิทธิตามกฎหมายว่า ด้วยข้อมูลข่าวสารของราชการหรือกฎหมายอื่นเพื่อขอเอกสารเกี่ยวกับข้อมูลด้านสุขภาพของบุคคลที่ไม่ใช่ ของตนไม่ได้

มาตรา 9 ในกรณีที่ผู้ประกอบวิชาชีพด้านสาธารณสุขประสงค์จะใช้ผู้รับบริการเป็นส่วนหนึ่งของการทดลอง ในงานวิจัย ผู้ประกอบวิชาชีพด้านสาธารณสุขต้องแจ้งให้ผู้รับบริการทราบล่วงหน้า และต้องได้รับความ ยินยอมเป็นหนังสือจากผู้รับบริการก่อนจึงจะดำเนินการได้ ความยินยอมดังกล่าว ผู้รับบริการจะเพิกถอนเสีย เมื่อใดก็ได้





# พระราชบัญญัติคุ้มครองข้อมูลส่วนบุคคล พ.ศ. 2562 PDPA

#### วัตถุประสงค์และฐานทางกฎหมายการประมวลผลข้อมูลส่วนบุคคล

มาตรา 26 ห้ามมิให้เก็บรวบรวมข้อมูลส่วนบุคคลเกี่ยวกับเชื้อชาติ เผ่าพันธุ์ ความคิดเห็นทางการเมือง ความเชื่อในลัทธิ ศาสนาหรือ ปรัชญา พฤติกรรมทางเพศ ประวัติอาชญากรรม ข้อมูลสุขภาพ ความพิการ ข้อมูลสหภาพแรงงาน ข้อมูลพันธุกรรม ข้อมูลชีวภาพ หรือ ข้อมูลอื่นใดซึ่งกระทบต่อเจ้าของข้อมูลส่วนบุคคลในทำนองเดียวกันตามที่คณะกรรมการประกาศกำหนด โดยไม่ได้รับความยินยอมโดย ชัดแจ้งจากเจ้าของข้อมูลส่วนบุคคล เว้นแต่

- (5) เป็นการจำเป็นในการปฏิบัติตามกฎหมายเพื่อให้บรรลุวัตถุประสงค์เกี่ยวกับ
- (ง) การศึกษาวิจัยทางวิทยาศาสตร์ ประวัติศาสตร์ หรือสถิติ หรือประโยชน์สาธารณะอื่น ทั้งนี้ ต้องกระทำเพื่อให้บรรลุวัตถุประสงค์ดังกล่าว เพียงเท่าที่จำเป็นเท่านั้น และได้จัดให้มีมาตรการที่เหมาะสมเพื่อคุ้มครองสิทธิขั้นพื้นฐานและประโยชน์ของเจ้าของข้อมูลส่วนบุคคล ตามที่ คณะกรรมการประกาศกำหนด

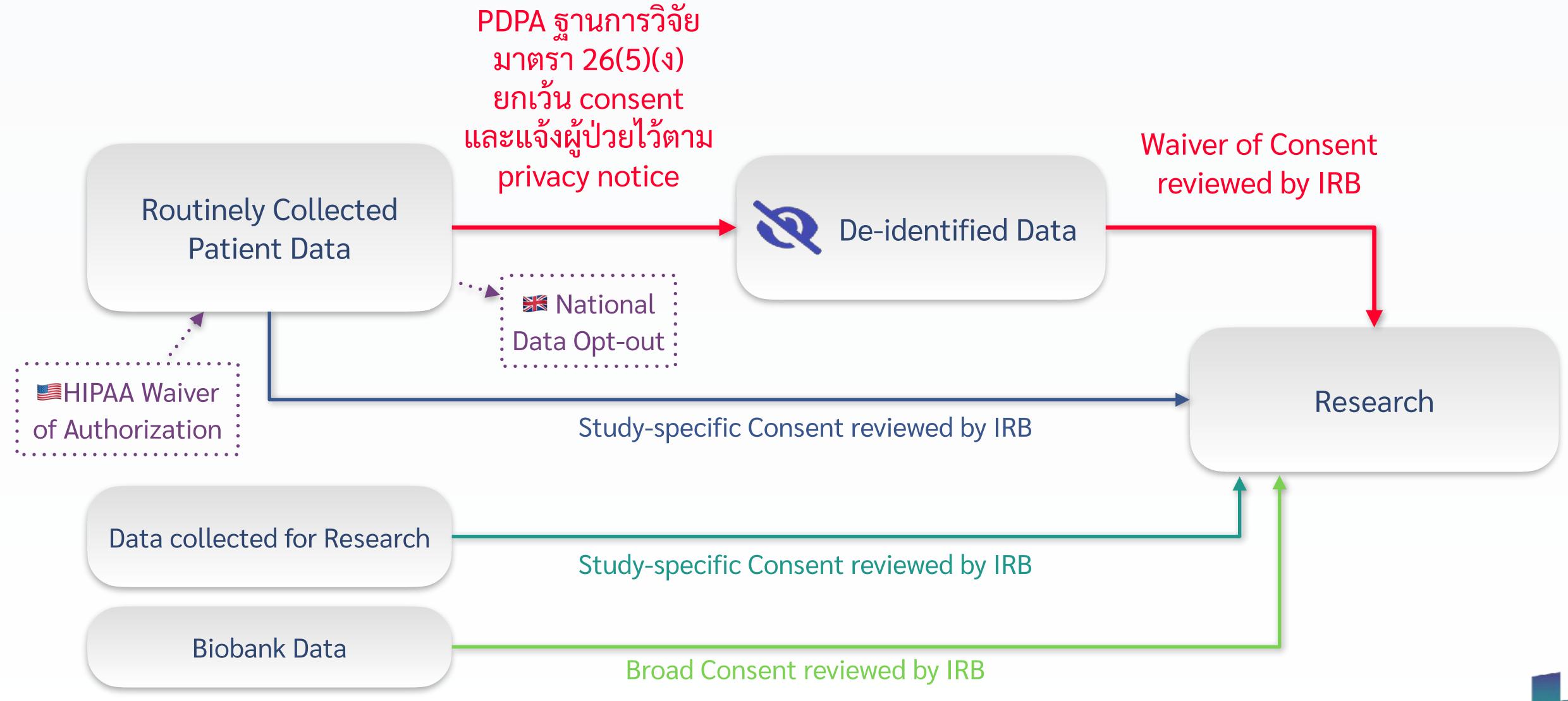
#### สิทธิของเจ้าของข้อมูลส่วนบุคคล ตามพระราชบัญญัติฯ

มาตรา 32 เจ้าของข้อมูลส่วนบุคคลมีสิทธิคัดค้านการเก็บรวบรวม ใช้ หรือเปิดเผยข้อมูลส่วนบุคคลที่เกี่ยวกับตนเมื่อ ใดก็ได้ ดังต่อไปนี้

(3) กรณีที่เป็นการเก็บรวบรวม ใช้ หรือเปิดเผยข้อมูลส่วนบุคคลเพื่อวัตถุประสงค์เกี่ยวกับการศึกษาวิจัยทางวิทยาศาสตร์ ประวัติศาสตร์ หรือสถิติ เว้นแต่เป็นการจำเป็นเพื่อการดำเนินภารกิจเพื่อประโยชน์สาธารณะของผู้ควบคุมข้อมูลส่วนบุคคล

### Mahidol University Faculty of Medicine Siriraj Hospital

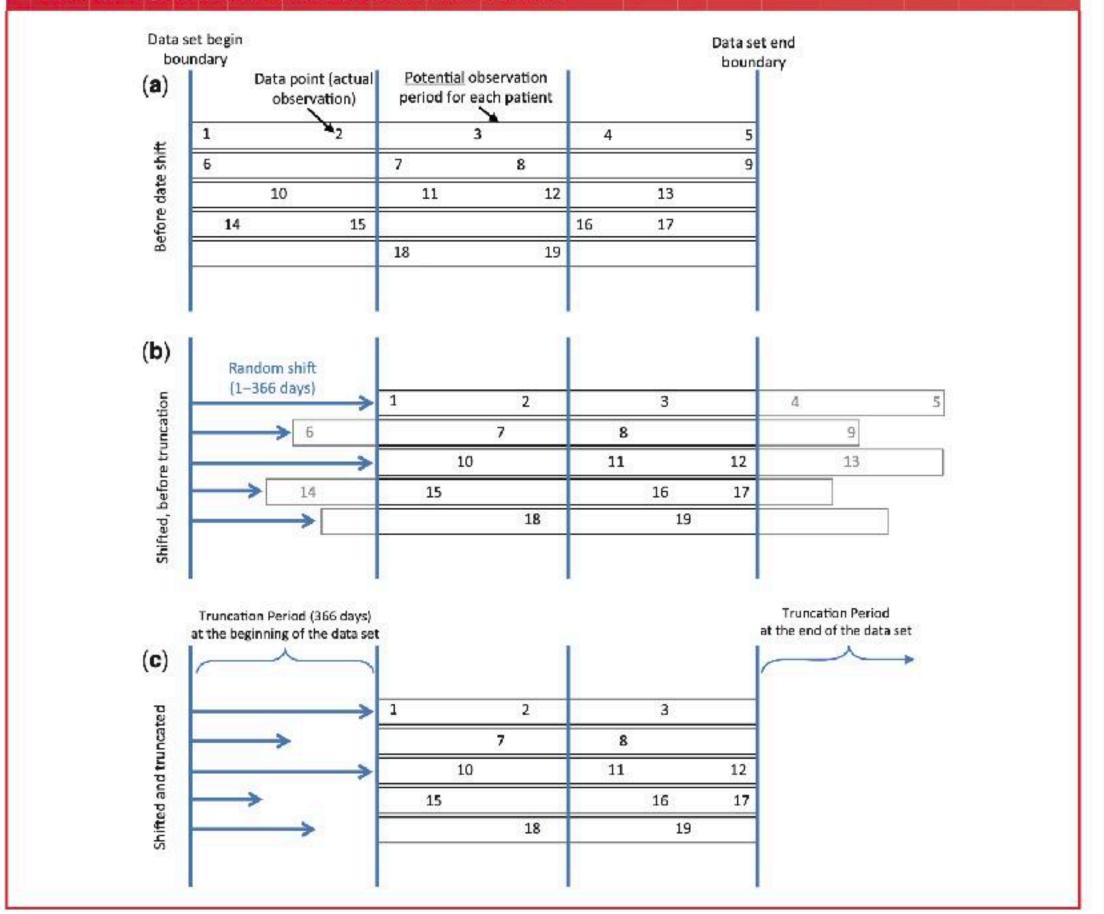
## รูปแบบการขอ consent การวิจัย จากข้อมูลชนิดต่าง ๆ



### Shift and Truncate (SANT) for De-identification



Figure 1: Shift and Truncate. Each row is a unique patient, each number is a unique data point for a patient, and each rectangle represents the time that the patient was potentially observed. (a) Original data set. Patients are potentially observed for 3 years (each vertical line marks 1 year). Patients need not have data, but simply the potential to have been observed (even if they lived elsewhere or were not born yet, someone had the potential to have been observed). (b) Shifted data set. Patient records are shifted forward by 1-366 days. Data points that were previously aligned across patients are no longer aligned, but points within a given patient remain at the same relative distances from each other. (c) Shifted and truncated data set. Data points from the first 366 days of the shifted data set and from the last 366 days of the shifted data set are removed from the data set.



#### Preserving temporal relations in clinical data while maintaining privacy

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OXFORD

Objective Maintaining patient privacy is a challenge in large-scale observational research. To assist in reducing the risk of identifying study subjects through publicly available data, we introduce a method for obscuring date information for clinical events and patient characteristics.

Methods The method, which we call Shift and Truncate (SANT), obscures date information to any desired granularity. Shift and Truncate first assigns each patient a random shift value, such that all dates in that patient's record are shifted by that amount. Data are then truncated from the beginning and end of the data set.

Results The data set can be proven to not disclose temporal information finer than the chosen granularity. Unlike previous strategies such as a simple shift, it remains robust to frequent - even daily - updates and robust to inferring dates at the beginning and end of date-shifted data sets. Time-of-day may be retained or obscured, depending on the goal and anticipated knowledge of the data recipient.

Conclusions The method can be useful as a scientific approach for reducing re-identification risk under the Privacy Rule of the Health Insurance Portability and Accountability Act and may contribute to qualification for the Safe Harbor implementation.



**ABSTRACT** 









### Secure Remote Research Environment



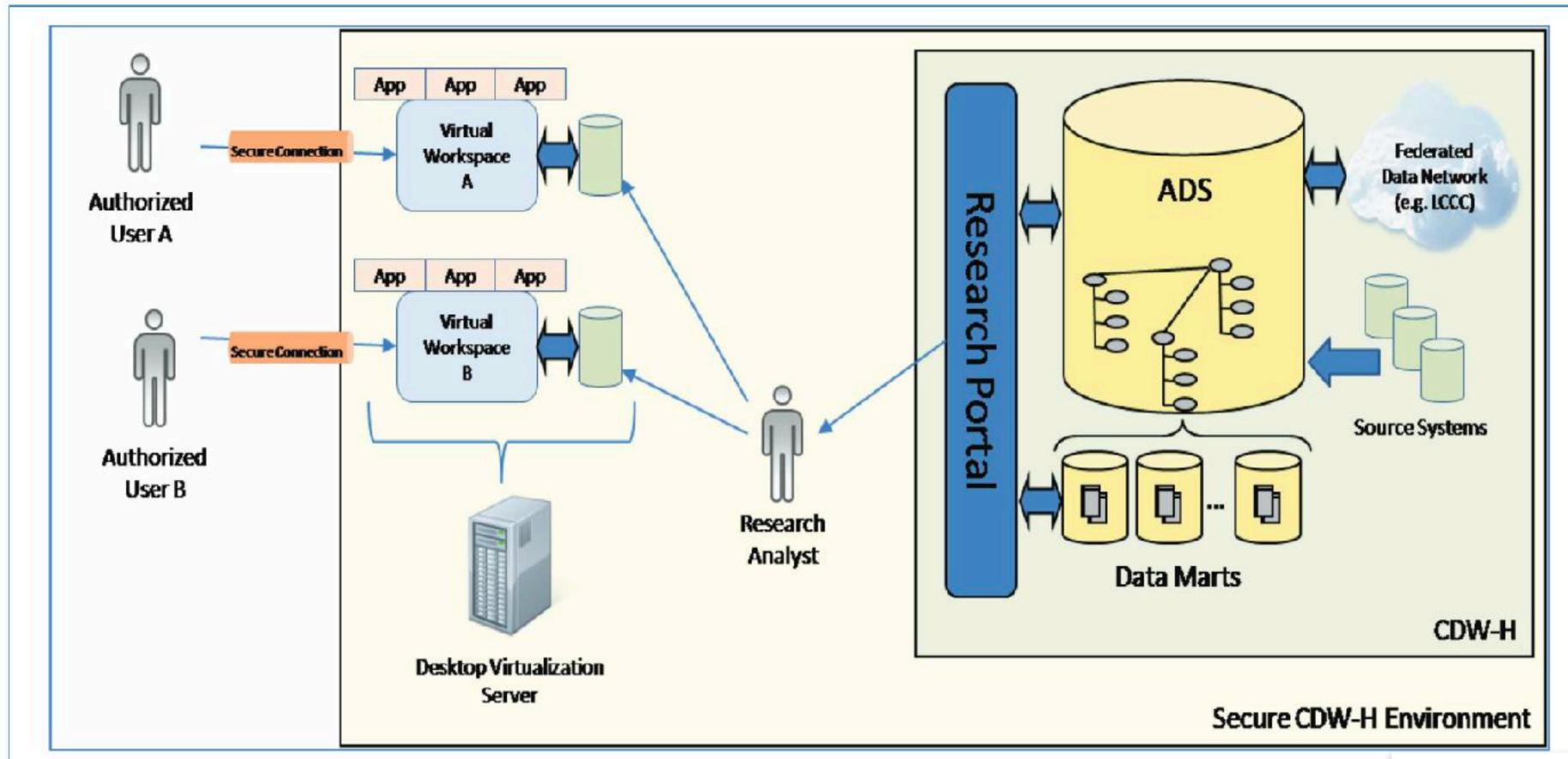




Figure 2. Conceptual view of the SMRW environment.

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The Secure Medical Research Workspace: An IT Infrastructure to Enable Secure Research on Clinical Data

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## Networking Event









## OHDSI Thailand Chapter?





