



Observational Health Data Sciences and Informatics, Interoperability, and Research

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Observational Health Data Sciences and Informatics



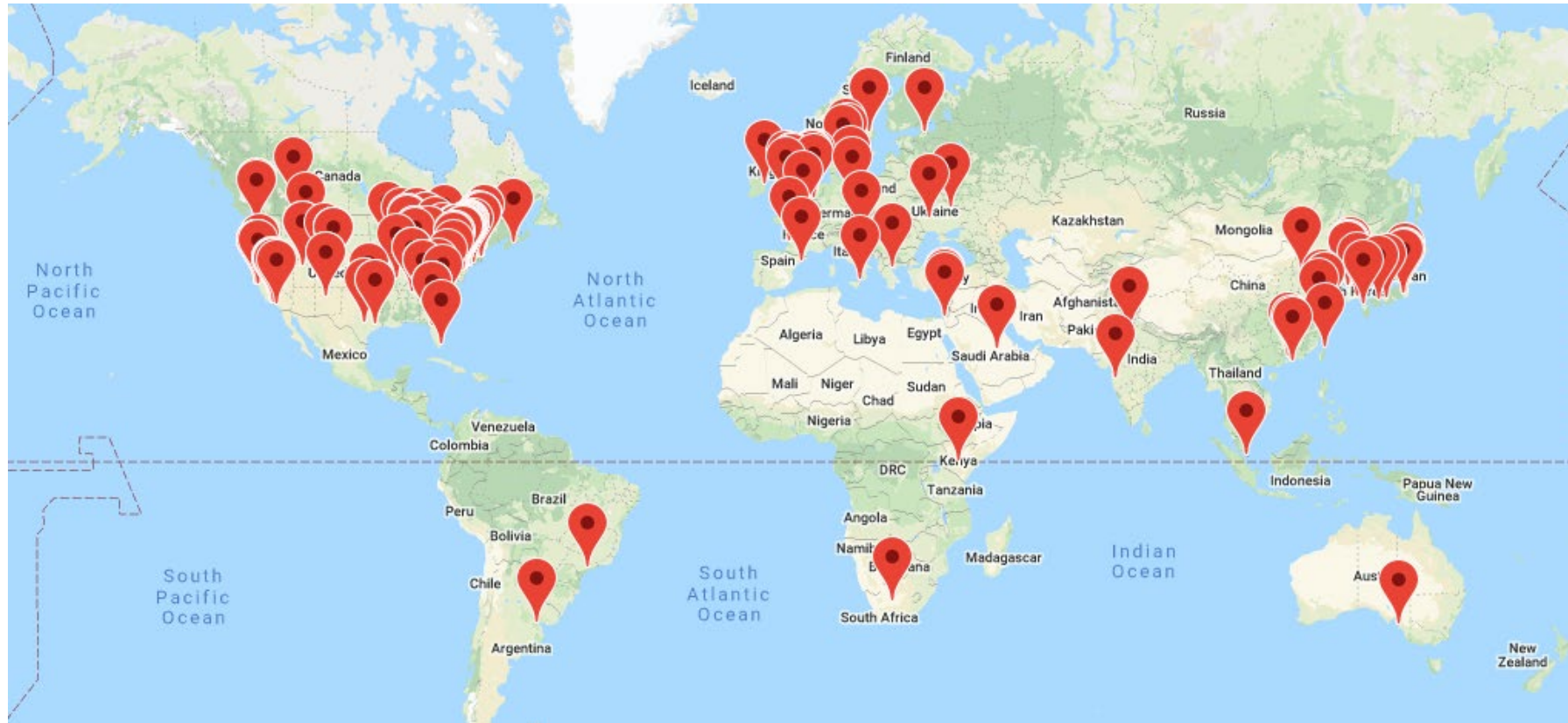
Observational Health Data Sciences and Informatics (OHDSI, as “Odyssey”)

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

A multi-stakeholder, interdisciplinary, international collaborative with a coordinating center at Columbia University



OHDSI's global research community



- >300 collaborators from 30 different countries
- Experts in informatics, statistics, epidemiology, clinical sciences
- Active participation from academia, government, industry, providers
- Records on about 600 million unique patients in >100 databases

<http://ohdsi.org/who-we-are/collaborators/>

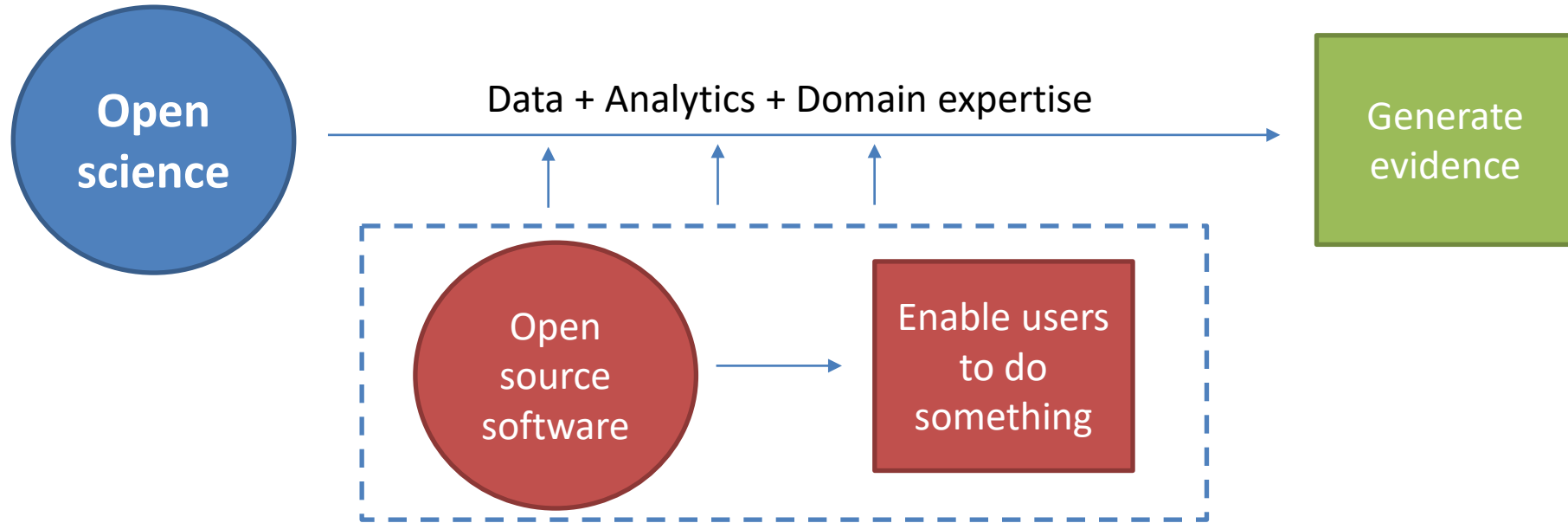


Evidence OHDSI seeks to generate from observational data

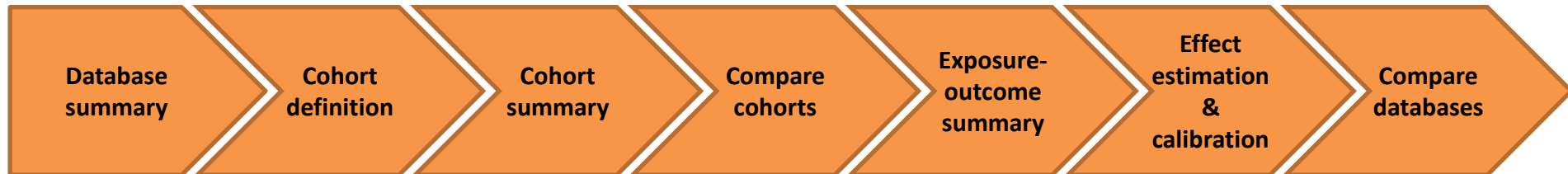
- **Clinical characterization - tally**
 - Natural history: Who has diabetes, and who takes metformin?
 - Quality improvement: What proportion of patients with diabetes experience complications?
- **Population-level estimation - cause**
 - Safety surveillance: Does metformin cause lactic acidosis?
 - Comparative effectiveness: Does metformin cause lactic acidosis more than glyburide?
- **Patient-level prediction - predict**
 - Precision medicine: Given everything you know about me, if I take metformin, what is the chance I will get lactic acidosis?
 - Disease interception: Given everything you know about me, what is the chance I will develop diabetes?



Open Science

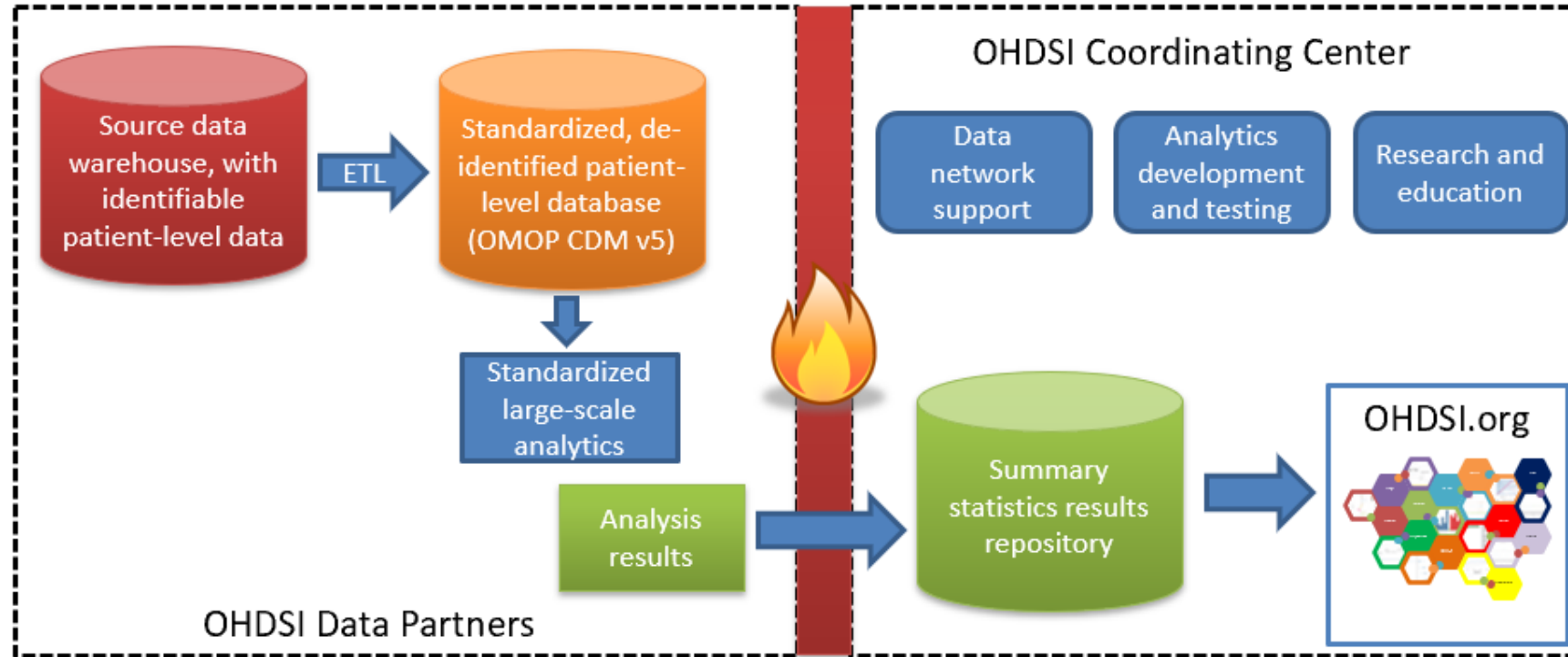


Standardized, transparent workflows



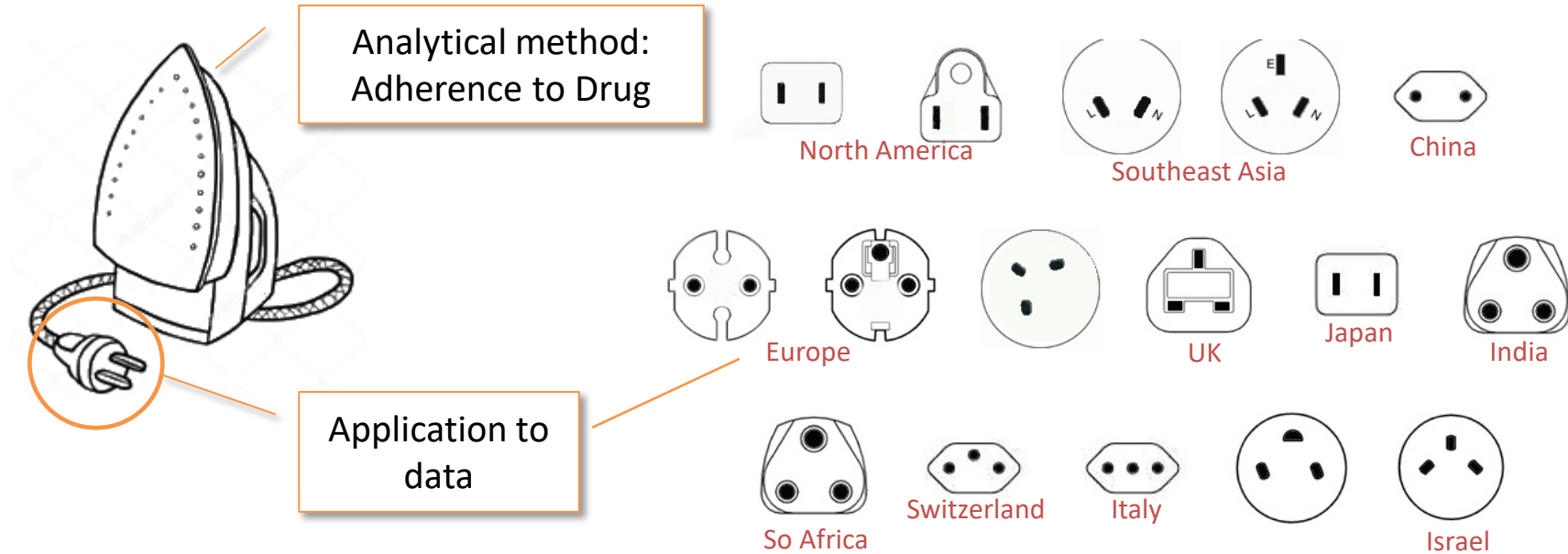


How OHDSI Works

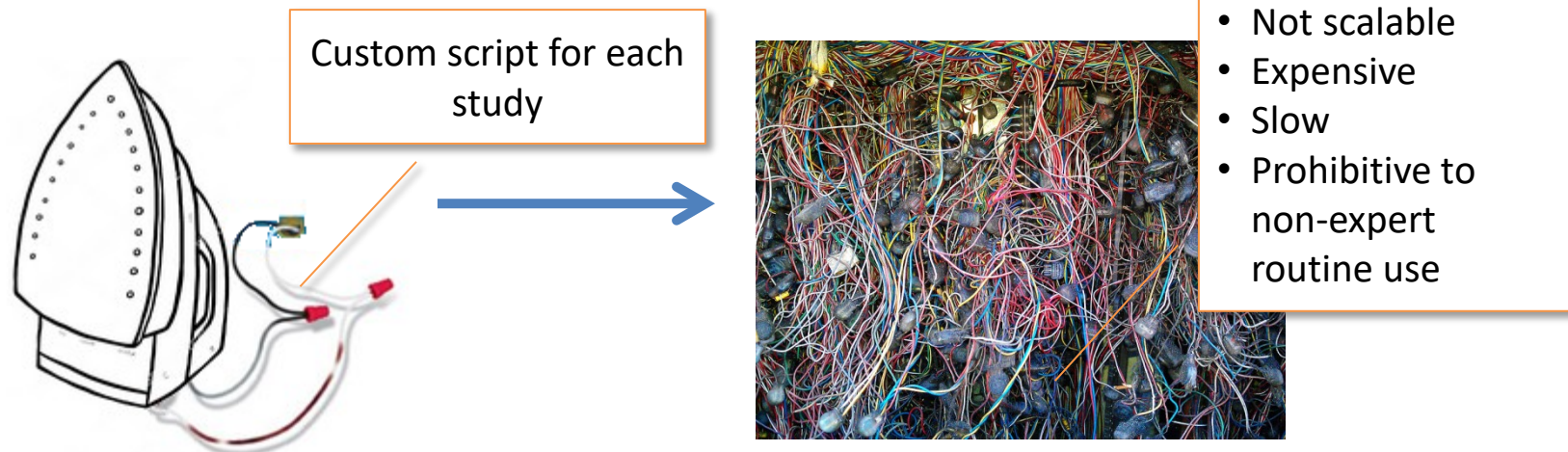


Current Approach: "One Study – One Script"

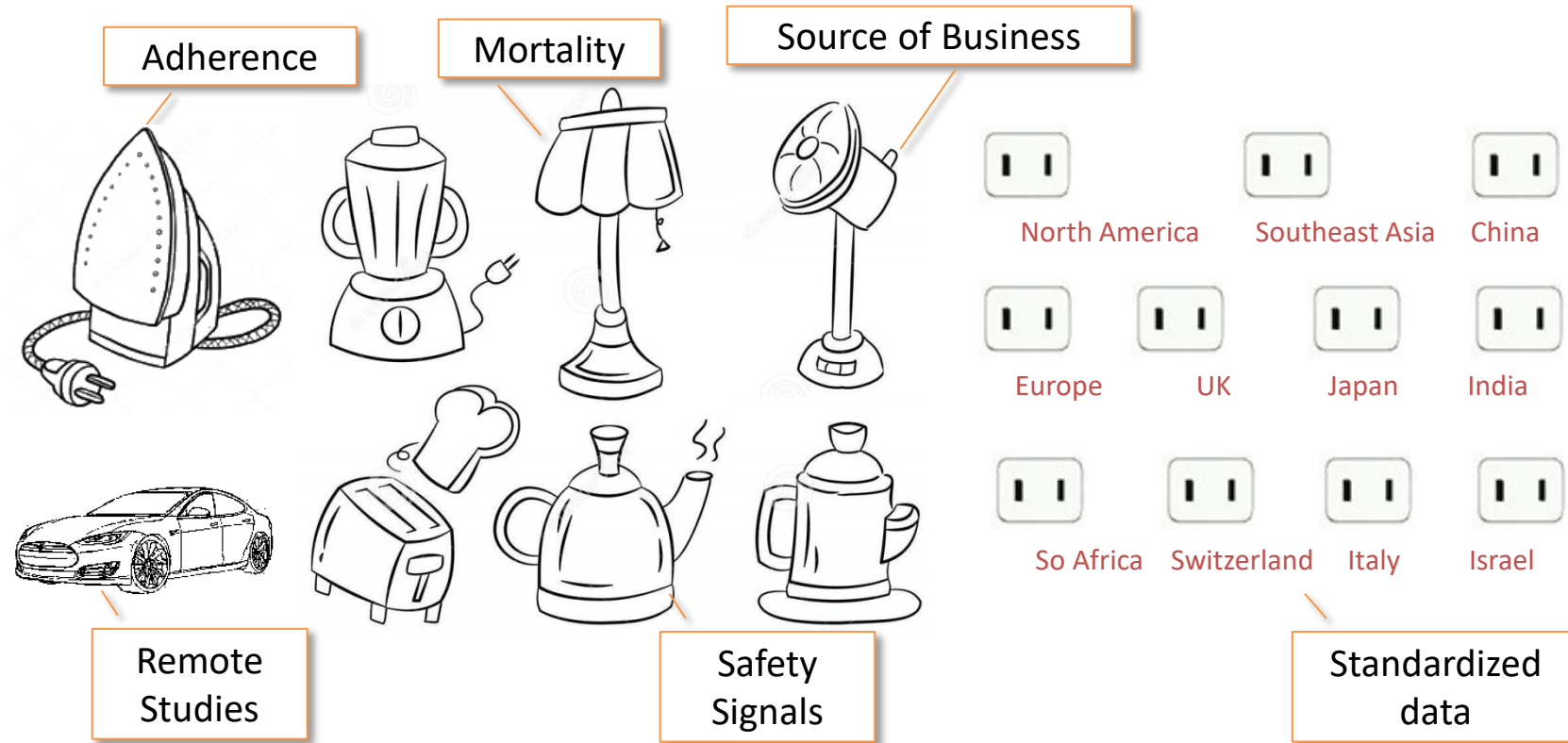
"What's the adherence to my drug in the data assets I own?"



Current solution:



Solution: Standardized Data and Analytics



1. ATLAS, Remote Studies
 - Standard Cohorts
 - Standardized Analytics

2. OMOP CDM
 - Standardized Format
 - Standardized Coding



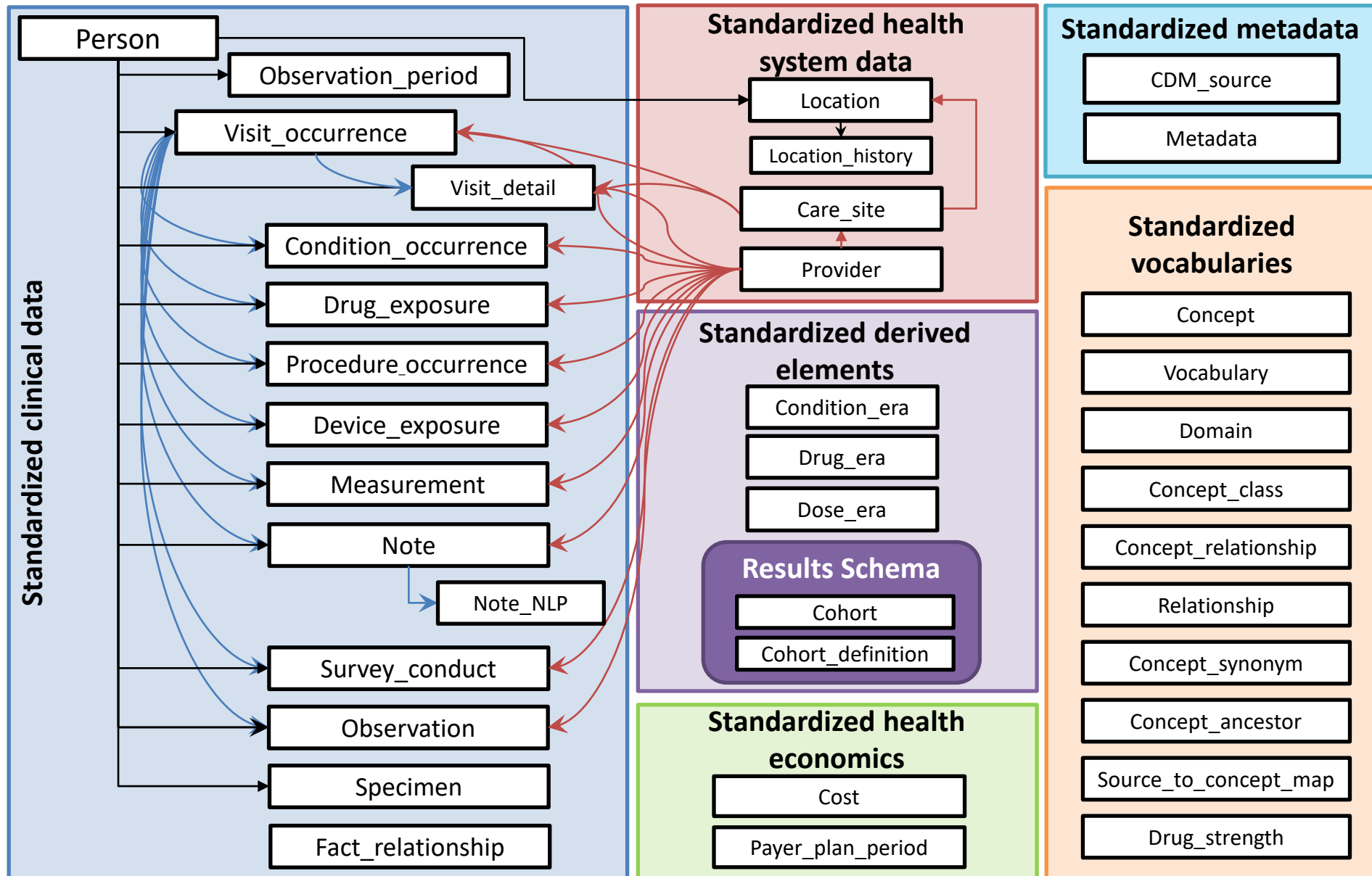
Common Data Model

- OMOP
 - Observational Medical Outcomes Partnership
 - (Origin of OHDSI; kept the data model name)
- Components
 - **Schema** – tables where you put data
 - **Vocabulary** – what codes go in the table
 - **Conventions** – how to store data
- Open committee structure to govern it
 - Contracted vocabulary maintenance



Deep information model

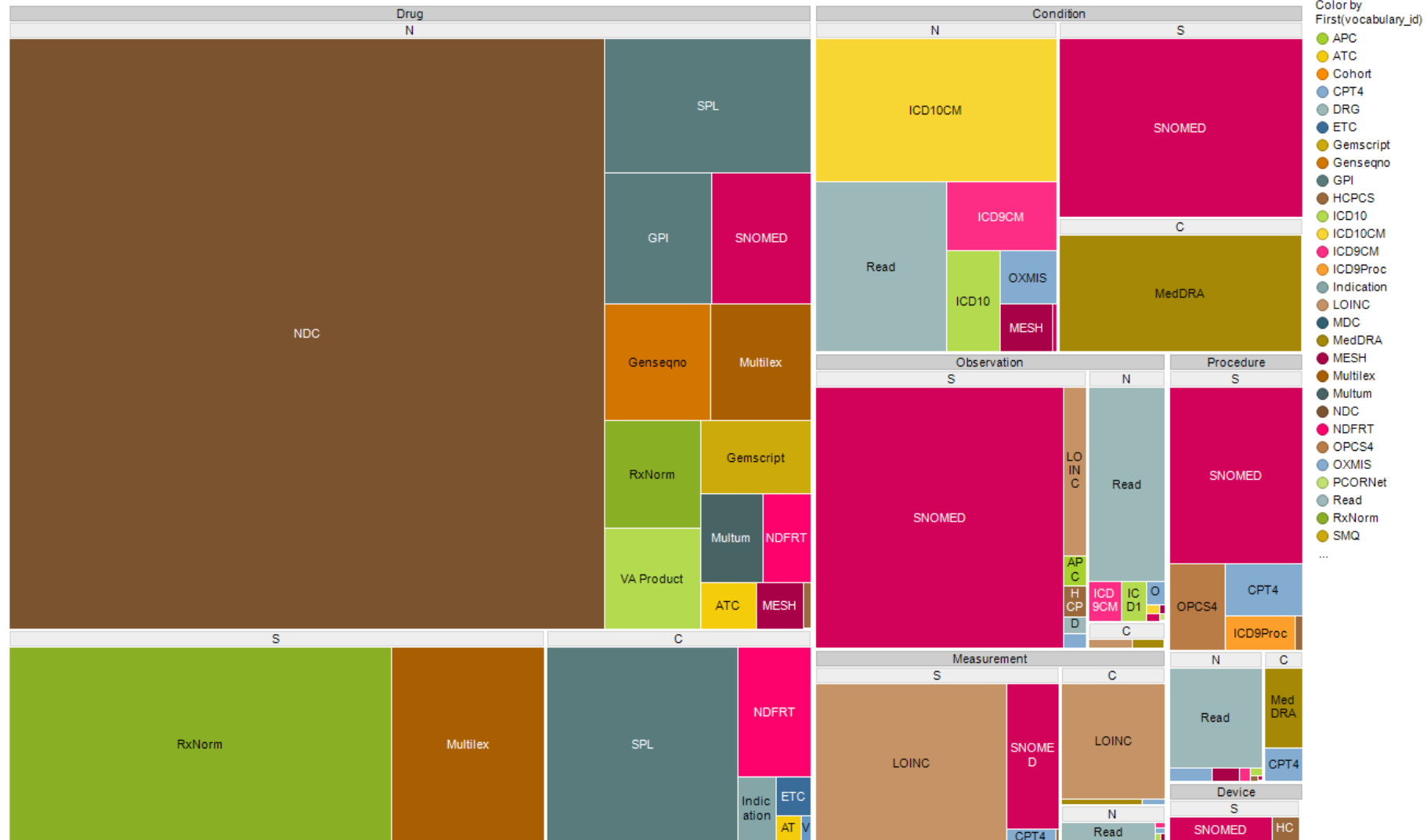
OMOP CDM





Extensive vocabularies

Breakdown of OHDSI concepts by domain, standard class, and vocabulary





OHDSI's standardized vocabularies

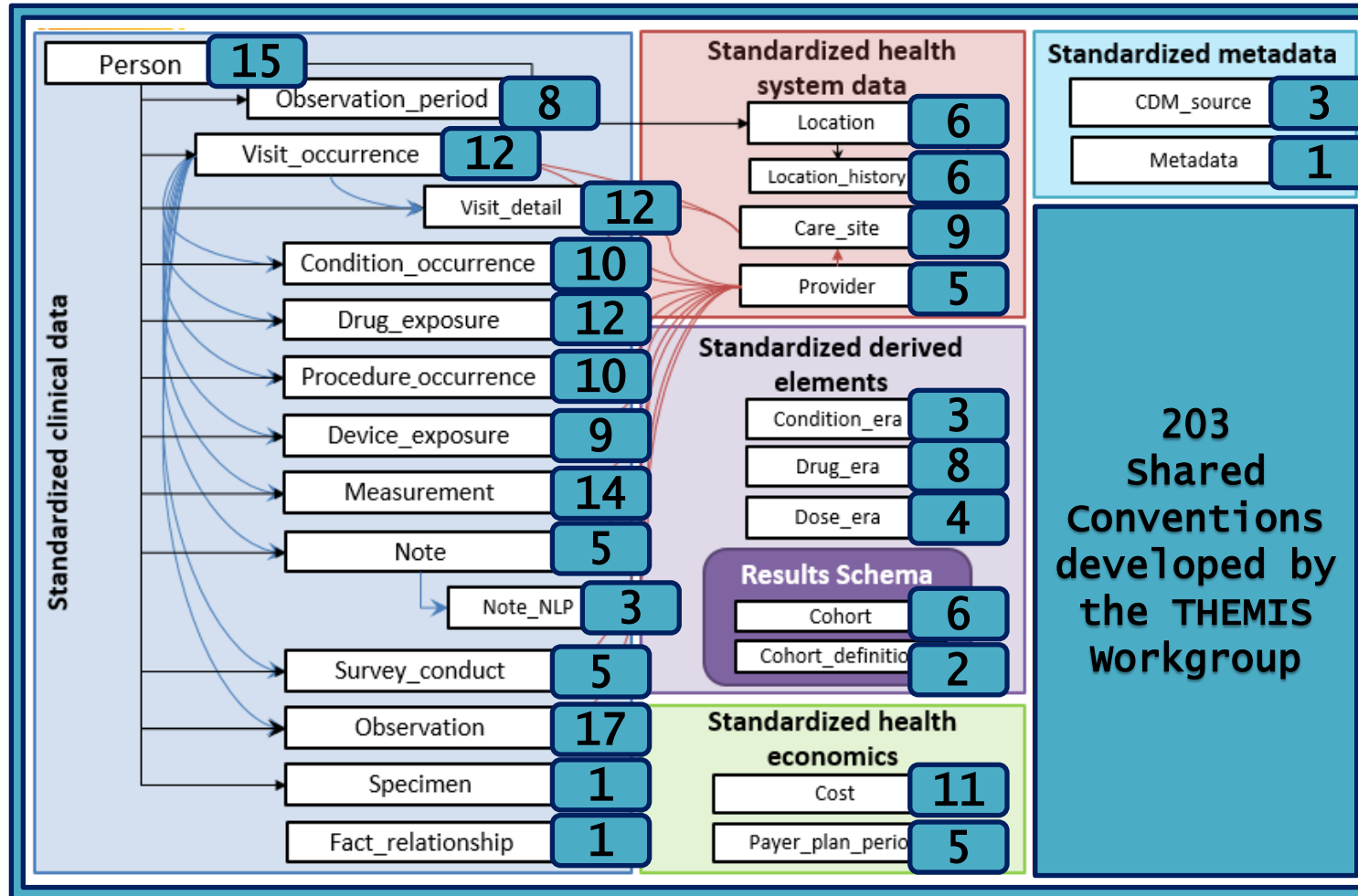
- 153 Vocabularies across 41 domains
 - MU3 standards: SNOMED, RxNorm, LOINC
 - Disparate sources: ICD9CM, ICD10(CM), Read, NDC, Gemscript, CPT4, HCPCS...
- >9 million concepts
 - >3.3 million standard concepts
 - >5.1 million source codes
 - >629,000 classification concepts
- >55 million concept relationships
- >84 million ancestral relationships



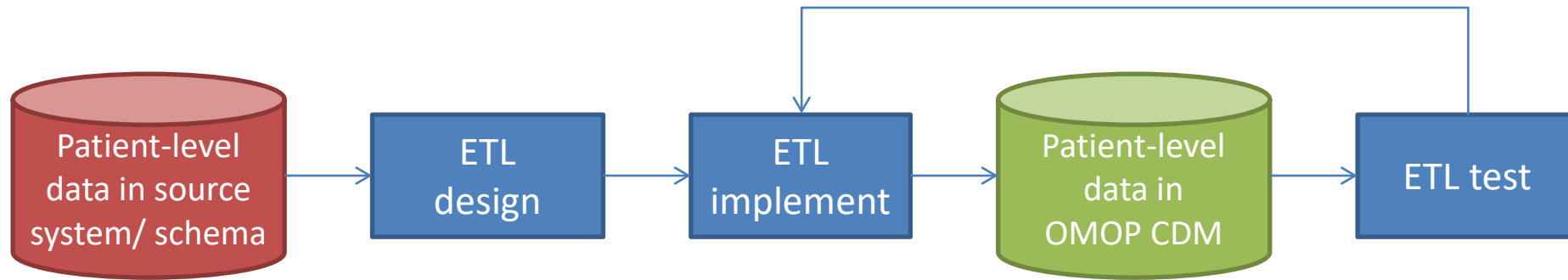
Standard vocabularies

- Bring the world's data to a core set
- RxNorm
 - RxNorm Extensions - cover non-US
- LOINC
- SNOMED CT
 - How to address non-US data
- In many areas, stuck adopting several
 - Procedures, ...

Standardized conventions



Preparing your data



OHDSI tools built to help

WhiteRabbit:
profile your source data

RabbitInAHat:
map your source structure to CDM tables and fields

ATHENA:
standardized vocabularies for all CDM domains

Usagi:
map your source codes to CDM vocabulary

CDM:
DDL, index, constraints for Oracle, SQL Server, PostgreSQL; Vocabulary tables with loading scripts

ACHILLES:
profile your CDM data; review data quality assessment; explore population-level summaries

OHDSI Forums:

Public discussions for OMOP CDM Implementers/developers

<http://github.com/OHDSI>



Data Quality Dashboard



IBM® MARKETSCAN® MULTI-STATE MEDICAID DATABASE

- OVERVIEW
- METADATA
- RESULTS**
- ABOUT

IBM® MARKETSCAN® MULTI-STATE MEDICAID DATABASE

DataQualityDashboard Version: 1.0.0

Results generated at 2020-08-24 15:44:34 in 3 hours

Column visibility CSV

Show entries

Search:

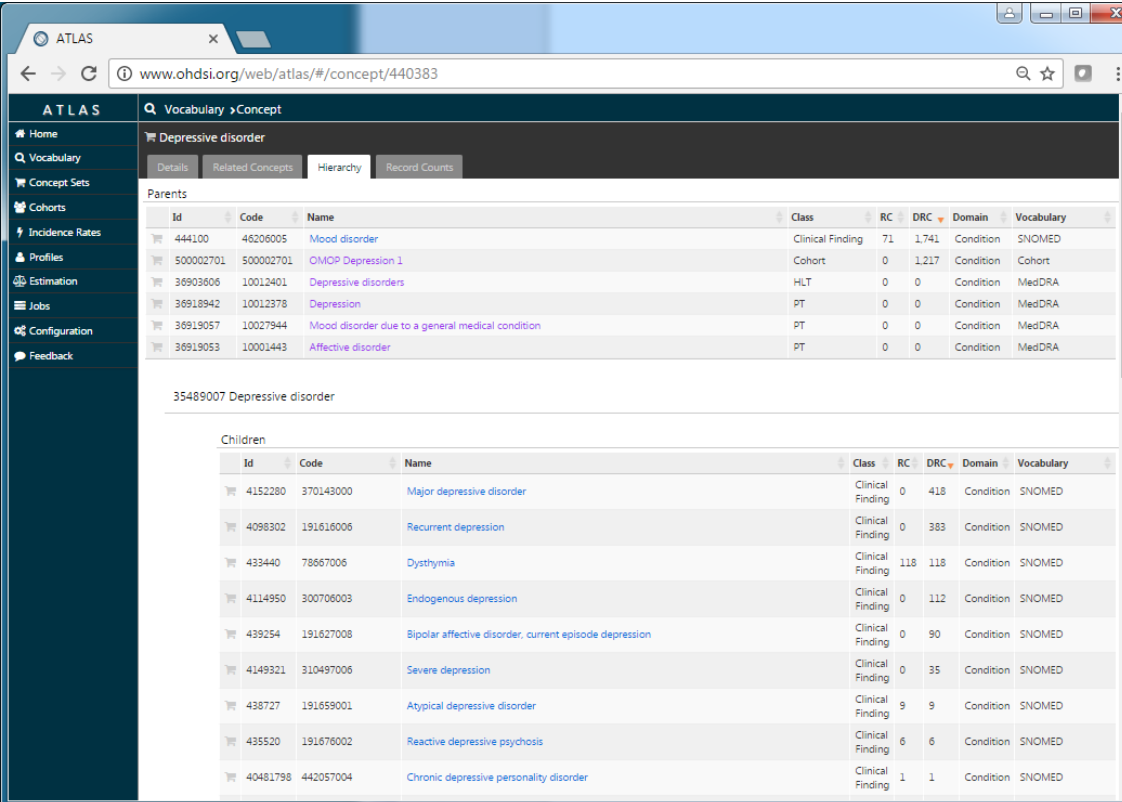
	STATUS	TABLE	CATEGORY	SUBCATEGORY	LEVEL	NOTES	DESCRIPTION	% RECORDS
<input type="checkbox"/>	FAIL	PAYER_PLAN_PERIOD	Conformance	Relational	FIELD	None	The number and percent of records that have a value in the payer_plan_period_id field in the PAYER_PLAN_PERIOD table that does not exist in the PERSON table. (Threshold=0%).	100.00%
<input type="checkbox"/>	FAIL	PROVIDER	Conformance	None	FIELD	None	The number and percent of records that do not have a standard, valid concept in the gender_concept_id field in the PROVIDER table. (Threshold=0%).	100.00%
<input type="checkbox"/>	PASS	PERSON	Completeness	None	FIELD	None	The number and percent of records with a NULL value in the birth_datetime of the PERSON. (Threshold=100%).	100.00%
<input type="checkbox"/>	PASS	PERSON	Completeness	None	FIELD	None	The number and percent of records with a NULL value in the provider_id of the PERSON. (Threshold=100%).	100.00%
<input type="checkbox"/>	PASS	PERSON	Completeness	None	FIELD	None	The number and percent of records with a NULL value in the care_site_id of the PERSON. (Threshold=100%).	100.00%

Showing 1 to 5 of 3,124 entries

Previous ... Next

ATLAS: Ontology support

- What terms do I need to create a cohort
- Tied to the database: what terms are used
 - Especially important for someone *else's* database



The screenshot shows the ATLAS web interface for the concept 'Depressive disorder'. The browser address bar shows the URL www.ohdsi.org/web/atlas/#/concept/440383. The interface includes a navigation sidebar on the left and a main content area with tabs for 'Details', 'Related Concepts', 'Hierarchy', and 'Record Counts'. The 'Hierarchy' tab is active, displaying a table of 'Parents' and a section for 'Children'.

Parents

Id	Code	Name	Class	RC	DRC	Domain	Vocabulary
444100	46206005	Mood disorder	Clinical Finding	71	1,741	Condition	SNOMED
500002701	500002701	OMOP Depression 1	Cohort	0	1,217	Condition	Cohort
36903606	10012401	Depressive disorders	HLT	0	0	Condition	MedDRA
36918942	10012378	Depression	PT	0	0	Condition	MedDRA
36919057	10027944	Mood disorder due to a general medical condition	PT	0	0	Condition	MedDRA
36919053	10001443	Affective disorder	PT	0	0	Condition	MedDRA

35489007 Depressive disorder

Children

Id	Code	Name	Class	RC	DRC	Domain	Vocabulary
4152280	370143000	Major depressive disorder	Clinical Finding	0	418	Condition	SNOMED
4098302	191616006	Recurrent depression	Clinical Finding	0	383	Condition	SNOMED
433440	78667006	Dysthymia	Clinical Finding	118	118	Condition	SNOMED
4114950	300706003	Endogenous depression	Clinical Finding	0	112	Condition	SNOMED
439254	191627008	Bipolar affective disorder, current episode depression	Clinical Finding	0	90	Condition	SNOMED
4149321	310497006	Severe depression	Clinical Finding	0	35	Condition	SNOMED
438727	191659001	Atypical depressive disorder	Clinical Finding	9	9	Condition	SNOMED
435520	191676002	Reactive depressive psychosis	Clinical Finding	6	6	Condition	SNOMED
40481798	442057004	Chronic depressive personality disorder	Clinical Finding	1	1	Condition	SNOMED



ATLAS: Cohort building

- Optimized for observational research
 - Time series: who and *when* (vs classification)
 - Observation period, event timing
 - Assume a complex definition – Linearized AND-OR group

ATLAS

www.ohdsi.org/web/atlas/#/cohortdefinition/82352

applied to each cohort entry record to determine the end date when the person's episode no longer qualifies for the cohort.

All Cohort Entry Criteria Cohort Exit Criteria

Initial event cohort: Events are recorded time-stamped observations for the persons, such as drug exposures, conditions, procedures, measurements and visits. All events have a start date and end date, though some events may have a start date and end date with the same value (such as procedures or measurements). The event index date is set to be equal to the event start date.

People having any of the following: [Add Initial Event...](#)

a visit occurrence of Any Visit [Add](#) [Add criteria attribute...](#) [Delete Criteria](#)

with continuous observation of at least 0 days before and 5 days after event index date

Limit initial events to: all events per person.

Initial event inclusion criteria: From among the initial events, include:

People having all of the following criteria: [Add New Criteria...](#)

with exactly 0 occurrences of:
a condition occurrence of C Diff Diagnoses [Add](#) [Add criteria attribute...](#) [Delete Criteria](#)
starting between All days Before and 1 days After event index date and ending any time.

and with at least 1 occurrences of:
a condition occurrence of C Diff Diagnoses [Add](#) [Add criteria attribute...](#) [Delete Criteria](#)
starting between 2 days After and 30 days After event index date and ending any time.

Limit cohort of initial events to: earliest event per person.

[Remove initial event inclusion criteria](#)

Additional qualifying inclusion criteria: The qualifying cohort will be defined as all persons who have an initial event, satisfy the initial event inclusion criteria, and fulfill all additional qualifying inclusion criteria. Each qualifying inclusion criteria will be evaluated to determine the impact of the criteria on the attrition of persons from the initial cohort.

[New qualifying inclusion criteria](#) Please select a qualifying inclusion criteria to edit.

Limit qualifying cohort to: earliest event per person.

Cohort Exit Criteria

Cohort exit criteria: For all persons who entered the cohort, there must be a specification of when each person exits the cohort. A person must exit the cohort at the end of the observation period spanning the qualifying initial event start date, but additional cohort exit criteria may be also considered.

[Add a cohort exit criteria](#)

Index event

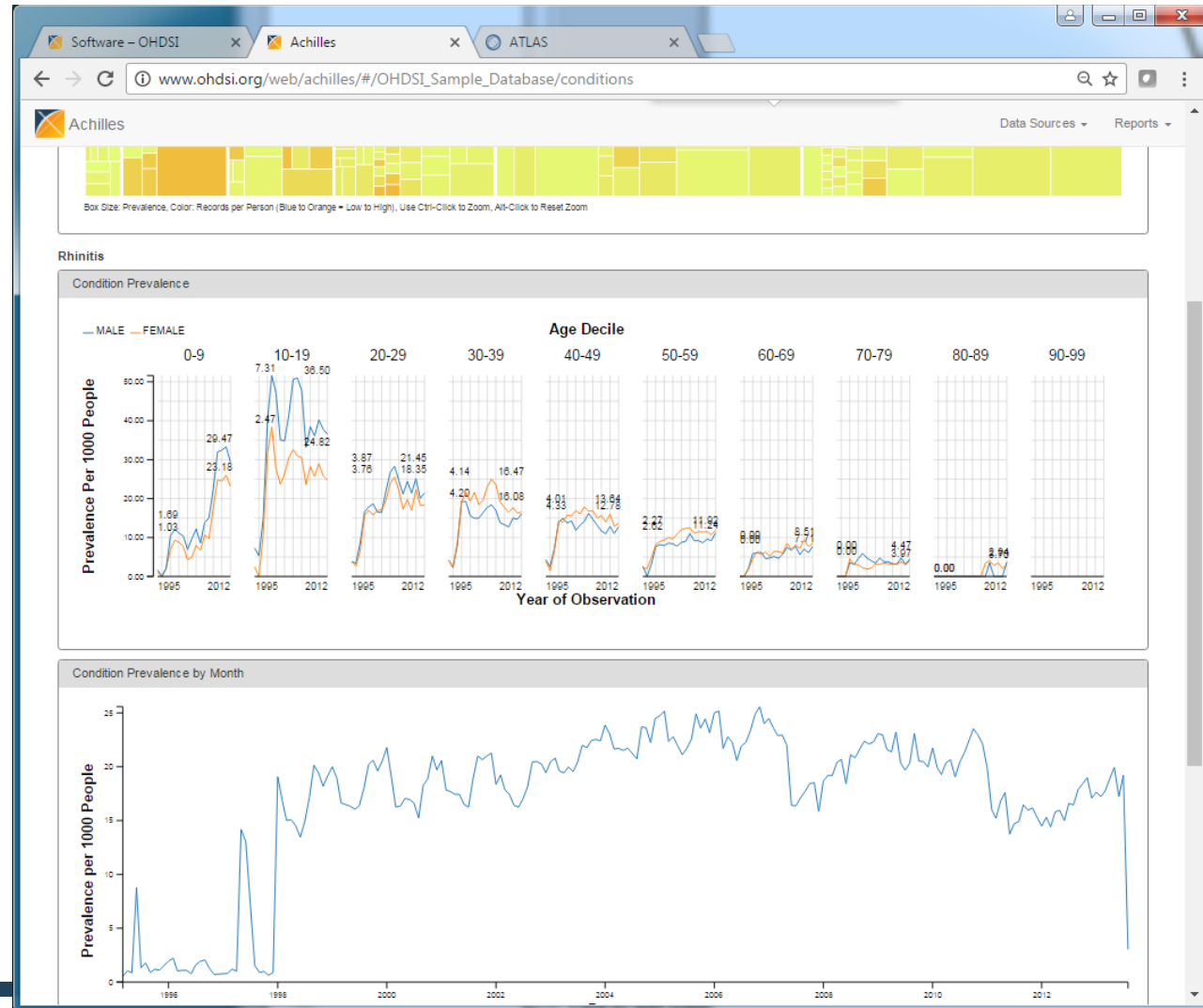
Criteria

Strata



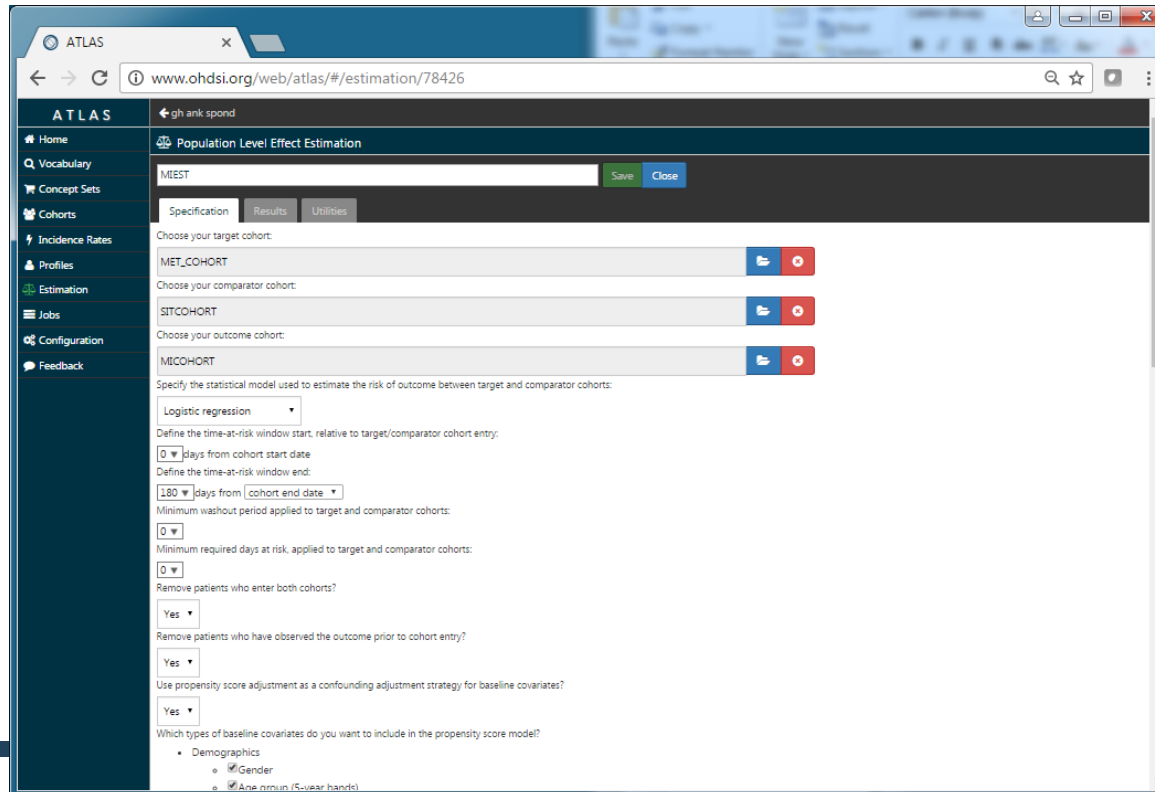
ATLAS: Visualization

- Tables
- Graphs



ATLAS: Analysis (observational)

- Approach: log regression, Poisson regression, survival
- Confounder: regularized-regression propensity score
- Residual confounding: calibration
- Diagnostics



The screenshot displays the ATLAS web interface for configuring a Population Level Effect Estimation. The browser address bar shows the URL www.ohdsi.org/web/atlas/#/estimation/78426. The interface includes a navigation sidebar on the left with options like Home, Vocabulary, Concept Sets, Cohorts, Incidence Rates, Profiles, Estimation, Jobs, Configuration, and Feedback. The main content area is titled "Population Level Effect Estimation" and features a "Specification" tab. A search bar contains the text "MIEST" with "Save" and "Close" buttons. Below this, there are three dropdown menus for selecting cohorts: "Choose your target cohort:" (MET_COHORT), "Choose your comparator cohort:" (SITCOHORT), and "Choose your outcome cohort:" (MICOHORT). Each dropdown has a blue arrow button and a red stop button. Further down, there are several configuration options with dropdown menus and checkboxes:

- Specify the statistical model used to estimate the risk of outcome between target and comparator cohorts: Logistic regression
- Define the time-at-risk window start, relative to target/comparator cohort entry: 0 days from cohort start date
- Define the time-at-risk window end: 180 days from cohort end date
- Minimum washout period applied to target and comparator cohorts: 0
- Minimum required days at risk, applied to target and comparator cohorts: 0
- Remove patients who enter both cohorts? Yes
- Remove patients who have observed the outcome prior to cohort entry? Yes
- Use propensity score adjustment as a confounding adjustment strategy for baseline covariates? Yes
- Which types of baseline covariates do you want to include in the propensity score model?
 - Demographics
 - Gender
 - Age group (5-year bands)



OHDSI in Action





OHDSI “LEGEND” Hypertension Study

Filling in the evidence gaps

Clinical Practice Guideline: Executive Summary

2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/
ASPC/NMA/PCNA Guideline for the Prevention, Detection,
Evaluation, and Management of High Blood Pressure
in Adults: Executive Summary

A Report of the American College of
Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

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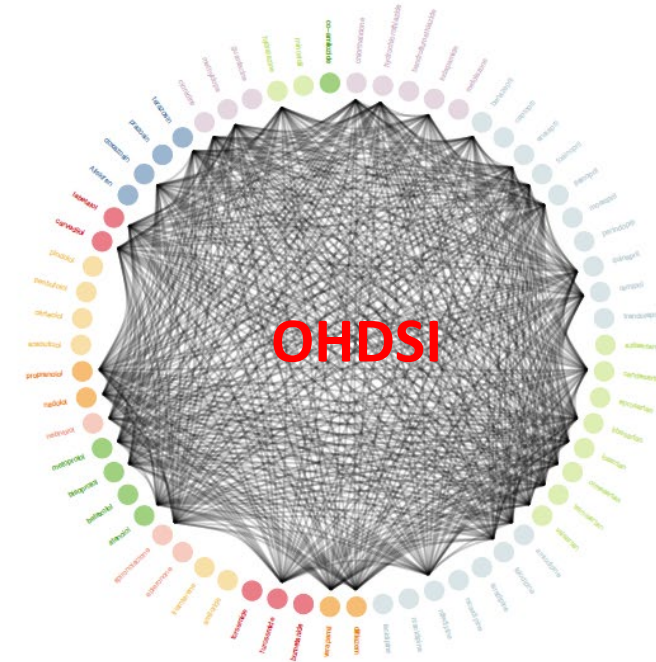
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Head-to-head HTN drug comparisons



- Trials: 40
- $N = 102 - [1148] - 33K$



- Comparisons: 10,278
- $N = 3502 - [212K] - 1.9M$

Hypertension, cardiac research

The Medical Letter[®]
on Drugs and Therapeutics

THE LANCET

Volume 394 · Number 10 211 · Pages 1779-1878 · November 16-22, 2019 www.thelancet.com

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, Jan Duke, David Madigan, George Hripcsak, Patrick B Ryan

Summary
Lancet 2019; 394: 1816-26
Published Online

Background Uncertainty remains about the optimal monotherapy for hypertension, with current guidelines recommending any primary agent among the first-line drug classes thiazide or thiazide-like diuretics, angiotensin-converting

Hypertension

BETA-BLOCKER THERAPY

Comprehensive Comparative Effectiveness and Safety of First-Line β -Blocker Monotherapy in Hypertensive Patients

A Large-Scale Multicenter Observational Study

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

ABSTRACT: Evidence for the effectiveness and safety of the third-generation β -blockers other than atenolol in hypertension remains scarce. We assessed the effectiveness and safety of β -blockers as first-line treatment for hypertension using 3

JAMA Internal Medicine

JAMA Internal Medicine | Original Investigation

Comparison of Cardiovascular and Safety Outcomes of Chlorthalidone vs Hydrochlorothiazide to Treat Hypertension

George Hripcsak, MD, MS; Marc A. Suchard, MD, PhD; Steven Shea, MD; Ruijun Chen, MD; Seng Chan You, MD; Nicole Pratt, PhD; David Madigan, PhD; Harlan M. Krumholz, MD, SM; Patrick B. Ryan, PhD; Martijn J. Schuemie, PhD

Supplemental content

IMPORTANCE Chlorthalidone is currently recommended as the preferred thiazide diuretic to treat hypertension, but no trials have directly compared risks and benefits.
OBJECTIVE To compare the effectiveness and safety of chlorthalidone and hydrochlorothiazide as first-line therapies for hypertension in real-world practice.

JAMA

JAMA | Original Investigation

Association of Ticagrelor vs Clopidogrel With Net Adverse Clinical Events in Patients With Acute Coronary Syndrome Undergoing Percutaneous Coronary Intervention

Seng Chan You, MD, MS; Yeunsook Rho, PhD; Behnood Bikhdeli, MD, MS; Jiwoo Kim, MS; Anastasios Siapos, MSc; James Weaver, MSc; Ajit Londhe, MPH; Jaehyeong Cho, BS; Jinyung Park, BS; Martijn Schuemie, PhD; Marc A. Suchard, MD, PhD; David Madigan, PhD; George Hripcsak, MD, MS; Aakriti Gupta, MD, MS; Christian G. Reich, MD; Patrick B. Ryan, PhD; Rae Woong Park, MD, PhD; Harlan M. Krumholz, MD, SM

IMPORTANCE Current guidelines recommend ticagrelor as the preferred P2Y12 platelet

Editorial page 1613

May 14, 2020

Take CME Exams

p 73
p 80a

1
terapy is a blood pressure of
nithypertensive drugs from
than baseline blood pressure
should be considered when
risk, eg,
anol blocker; an angiotensin-
or an angiotensin receptor
initial therapy in the general
cum channel blocker is
of black patients, except for
or heart failure, who should
intended for initial treatment
acts with diabetes. In the
de-
like diuretic or calcium
reasonable choice
an initial therapy only for
for a beta blocker, such as
a.
usually black patients, need
status. If the first drug does
adding a second drug with a
especially more effective than
2 and often allows for use of
of drug.
used initially, it is reasonable
alone channel blocker. Two
rbitors should not be used

ppertension

ACE inhibitor, ARB, or CCB
r CCB

ibitor or ARB
ibitor or ARB

ibitor or ARB
r CCB

2 = angiotensin receptor blocker;
CCB = diuretic; ARB = angiotensin
D should receive an ACE inhibitor



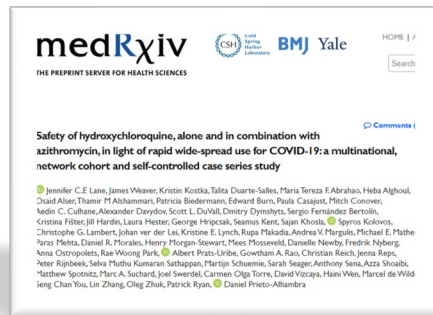
COVID-19 Research

- 4.5 million COVID-19 patient records
 - Academic centers (CDW)
 - EHR and claims data aggregators
 - Government databases
- 41 studies carried out in past year



Safety of hydroxychloroquine

- Evidence was needed around the use of hydroxychloroquine (HCQ) alone and in combination with azithromycin (AZ). We examined the use of these drugs in rheumatoid arthritis (RA) patients.
- Findings:
 - In history use in RA population, HCQ alone is generally safe but in combination with AZ it shows a doubling of risk of 30-day cardiovascular mortality.



ACE Inhibitors and susceptibility to COVID-19

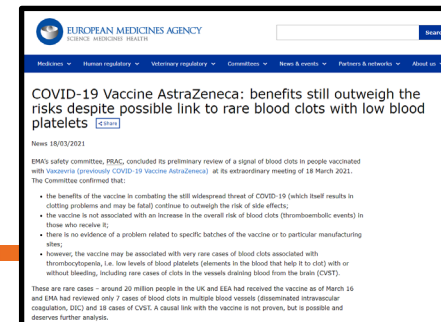
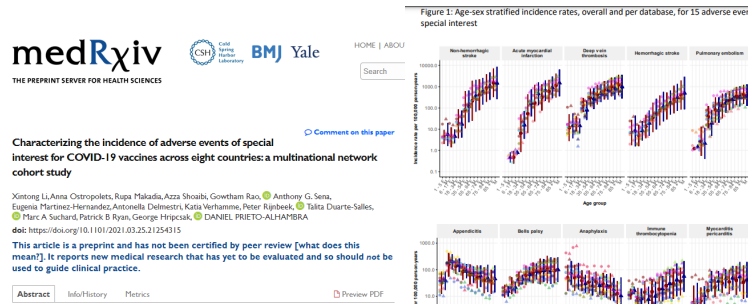
- Patients with cardiovascular diseases and hypertension treated with angiotensin converting enzyme inhibitors (ACEs) angiotensin-II receptor blockers (ARBs) may influence susceptibility to COVID-19 and worsen its severity.



As stated by [Watson et al.](#) in relation to one of the published studies, lack of transparency and uncertainties about research standards applied raise doubts about published results. [Morales et al.](#) supported the reproducibility of their study by publishing the study protocol in the [EU PAS Register](#) ahead of time, providing [a start-to-finish executable code](#), facilitating the sharing and exploration of the complete result set with an [interactive web application](#) and asking clinicians and epidemiologists to perform a blinded evaluation of propensity score diagnostics for the treatment comparisons.

COVID-19 Vaccine Safety Methods Research

- AstraZeneca vaccine
 - March 11-15, 2021 – 13 European countries suspend use for fears of blood clots
 - Denmark, Norway, Iceland, Bulgaria, Ireland, Netherlands, Spain, Germany, Italy, France, ...
 - As of March 16, 2021 – of 20 million persons vaccinated in Europe several deaths
 - 469 thromboembolic events reported after vaccination
 - 7 cases disseminated intravascular coagulation (DIC)
 - 18 cases cerebral venous sinus thrombosis (CVST)
 - March 18, 2021 – EMA determines benefits outweigh the risks
 - Thromboembolic events “lower than that **expected in the general population**”
 - DIC and CVST above baseline but very rare
 - “The number of reported events **exceeds those expected**, and causality although not confirmed, cannot therefore be excluded. However, given the rarity of the events, and the **difficulty of establishing baseline incidence** since COVID-19 itself is resulting in hospitalisations with thromboembolic complications, the strength of any association is uncertain.”
- Partnered with FDA Center for Biologics Evaluation and Research (CBER)
 - Vaccine safety methods research, network and local studies





OHDSI OMOP Common Data Model

FDA CBER BEST Program

FDA **Biologics Effectiveness and Safety (BEST) Initiative:**
Incorporating ISBT-128 Codes into OHDSI's OMOP Common Data Model to Build a National Hemovigilance System to Monitor Transfusion-Related Adverse Events

Joyce Ohlil, Himmeh Chahal, Joann Groden, Grupa Dower, Adam Williams, Emily Sheehy, Joann M Benda, Swadesh Gombosi, Deepa Bhatia, Ross Hayden, Paul Biondich, Shaun Granam, George Hefceck, Thomas Falconer, Karthik Natarajan, Dmitry Dymitryy, Sara Dempster, Christian Reich, Nandini Selvam, Melissa Williams, Steven Anderson, Azadeh Shoahri

*Center for Biologics Evaluation and Research, Food and Drug Administration, Silver Spring, MD, USA; †Stanford University, Stanford, CA, USA; ‡Regeneron Institute, Indianapolis, Indiana, USA; §Columbia University, New York, NY, USA; ¶Observational Health Data Sciences and Informatics, New York, NY, USA; **Oryzoun Data Services Inc., Cambridge, MA, USA

INTRODUCTION

The U.S. FDA Center for Biologics Evaluation and Research (CBER) regulates collection of whole blood and blood components utilized in transfusion¹.

CBER's Role in Blood Safety

To protect recipients of blood and blood components and to monitor transfusion-related adverse events (TRAE).

BEST Initiative

Biologics Effectiveness and Safety (BEST) Initiative is a component of the CBER Sentinel Program. The BEST Initiative is made up of a distributed network of data providers that use claims and electronic health record (EHR) data sources transformed into a common data model (CDM).

Infrastructure for Hemovigilance

The most detailed blood and blood components data are included in the Information Standard for Blood and Transplant (ISBT-128 coding system). In laying the infrastructure for a hemovigilance system, we incorporated the ISBT-128 coding system into the CDM used by the BEST Initiative.

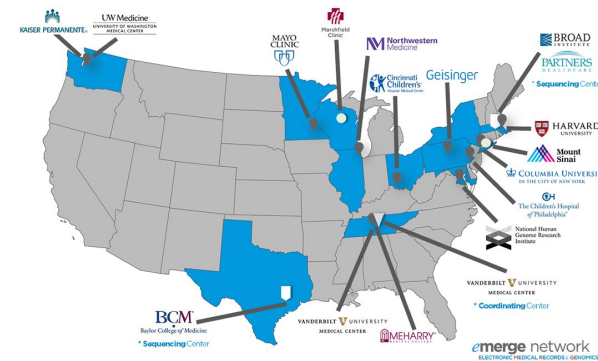
OBJECTIVE

The aim of this study was to build a component of the infrastructure for a national hemovigilance system using EHR data sources to monitor transfusion-related AEs by incorporating the ISBT-128 coding system into the Observational Medical Outcomes Partnership (OMOP) common data model (CDM) of the Observational Health Data Sciences and Informatics (OHDSI) consortium².

METHODS

The CBER BEST initiative is a collaboration with KQVIA, OHDSI Consortium, Columbia University, Stanford University, Indiana University, Regenstrief Institute, Georgia Institute of Technology, and University of California Los Angeles. Within the BEST Initiative, we used three EHR databases that cover approximately 24 million patient records from geographically diverse areas of the U.S. We added a library of 14,543 ISBT-128 codes to the OMOP CDM. Each EHR data source requested access to its corresponding blood bank data and transformed its data into the OMOP CDM containing the newly added ISBT-128 codes. By querying the database, we determined the type and frequency of ISBT-128 codes used in patient records from 2010-2017 within the blood banks of EHR data providers participating in the BEST Initiative.

eMERGE Network



All of Us Research Program

U.S. Department of Health & Human Services | National Institutes of Health

NIH National Institutes of Health
 All of Us Research Program

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The future of health begins with you

The *All of Us* Research Program is a historic effort to gather data from one million or more people living in the United States to accelerate research and improve health. By taking into account individual differences in lifestyle, environment, and biology, researchers will uncover paths toward delivering precision medicine.

[JOIN NOW](#)

N3C National COVID Cohort

National COVID Cohort Collaborative (N3C)

Image credit: NIAID

The N3C is a partnership among the NCI's supported Clinical and Translational Science Awards (CTSA) Program hubs and the National Center for Data to Health (NCDH), with several leadership by NCI's Collaborators will contribute and use COVID-19 clinical data to answer critical research questions to address the pandemic.

Building an Innovative Analytics Platform to Study COVID-19

The N3C is a new effort that aims to build a centralized national data resource that the research community can use to study COVID-19 and identify potential treatments as the pandemic continues to evolve.

Collaborations: PCORnet, S4S, ...



HL7 – OHDSI Partnership

- Announced March 1, 2021
 - FHIR and OMOP
 - “The organizations will align their standards to capture data in a clearly defined way into a single common data model. This will allow clinicians as well as researchers to pull data from multiple sources and compile it in the same structure without degradation of the information.”
- Early in creation of joint working groups and scope
 - Starting with existing mapping work
 - Georgia Tech, EHDEN, MIRACUM, Leiden University, Denmark CSS
- Range
 - Mapping, shared knowledge engineering, common standard
- Welcome the feedback



Themes





Research as “secondary use”

- Research is not an afterthought
 - It drives health care and saves millions of lives
- Jonas Salk invented the polio vaccine
 - No one remembers his billing records
- Without research we would be billing for leeches
- Perhaps (after patient care) research should become paramount and billing should make due



Mission

- You can store data or you can generate evidence, but you cannot do both



Coupling

- Therefore, need a tightly coupled enterprise, evidence generation & standards development
 - OHDSI governance structure
 - Need analytic standards as well as data
 - Standard must be connected to community
 - Open source



It's not magic

- Someone has to pay the data-quality price
 - In All of Us RP, found conversion is best close to data generation
 - FHIR dump of all data to a distance central warehouse will be tough



US-specific standards

- US is 5% of the population
 - Continued focus on US standards hurts US citizens
- Modern causal inference is data hungry
 - Cannot do most research on just the US population



Join the journey

<http://ohdsi.org>