2023: Year in Review
2013-2023: OHDSI 10-year birthday in review

Agenda

- Bring your favorite OHDSI swag
- 2023 Year in review (polleverwhere)
  - Jan - targets: vocab, data network, devt infrastructure,
  - Feb - Phenotype Pheb
  - Mar - software, publications
  - Apr- software, publications
  - May – SOS challenge
  - June - software, publications,
  - July - OHDSI EU and APAC
  - Aug- software, publications
  - Sept- software, publications
  - Oct - OHDSI US
  - Nov- software, publications
  - Dec- software, publications
  - Highlights: Faaizah – first paper; Ross, Alex, and Anna – finish PhD, Nicole – Beer, FDA workshop on negative controls , Europe – National nodes (polleverwhere)
- Decade in review
  - First meeting
  - First big network study – Txpathways
  - Book of OHDSI
  - LEGEND
  - Picture montage – symposia over years
  - COVID study-a-thon – impact on hydroxychloroquine
  - Fun times
    - Study-a-thons
    - US Closings
      - Dr. Suess
      - Cake
      - Study-in-a-day
      - Art
      - Weaves
      - Lego
      - Escape room / OHDSI Got Talent!
    - EU closings – Peter singing
    - APAC closing – Nicole Al Beer
  - Cameos
  - Cheers video
  - Blooper reel?
  - Legos video
  - Titans through the years
  - Happy Birthday
  - Cake
- Get people to share their favorite OHDSI memories – open mic

2023 In Review

Join by Web **PollEv.com/patrickryan800**

What was your favorite OHDSI highlight in 2023?

Nobody has responded yet.

Hang tight! Responses are coming in.

Looking back 12 months to our 2023 resolutions

Workgroups:

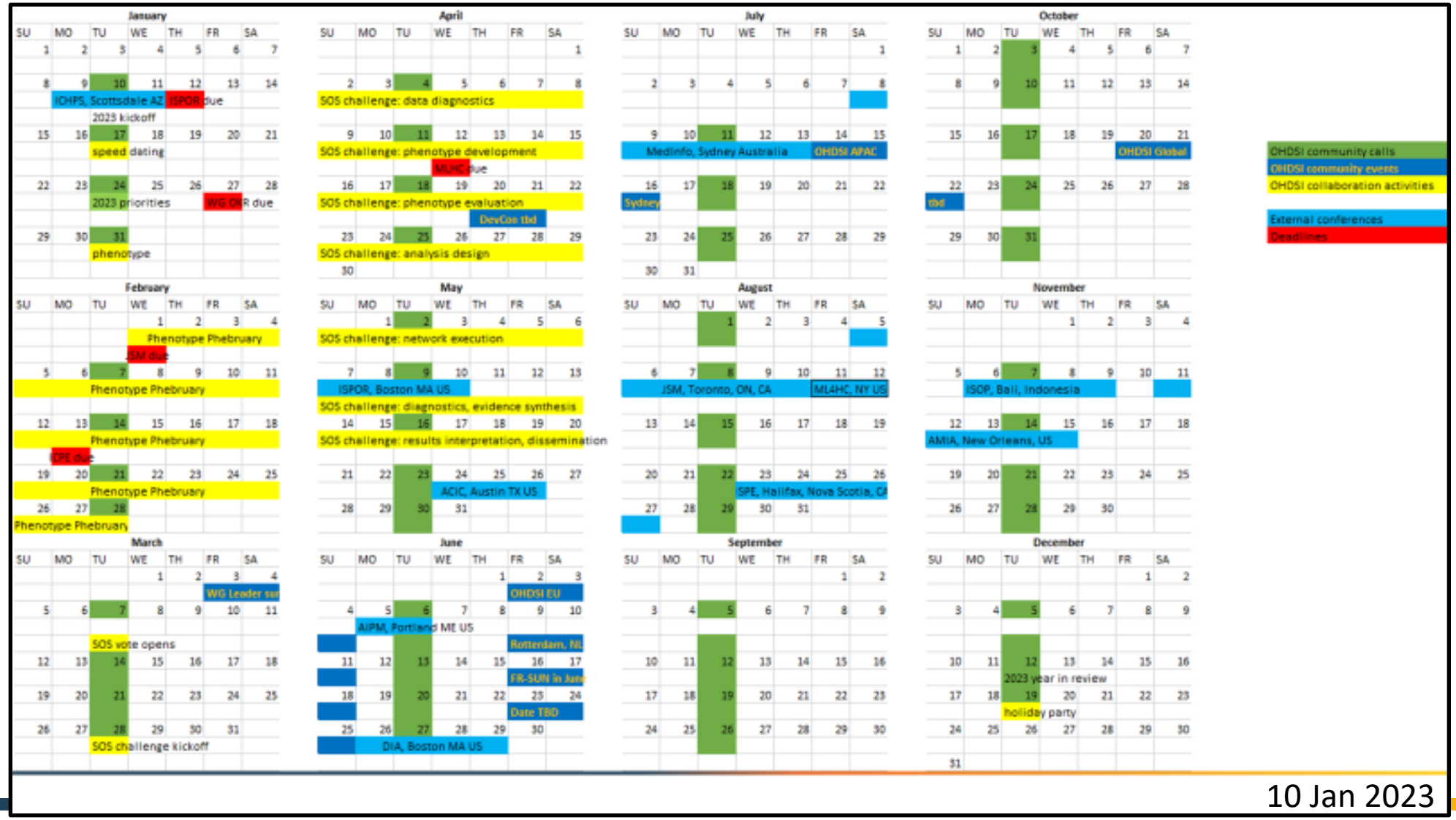
1) All workgroup leaders will provide their purpose and 2023 Objectives and Key Results by end of January
2) All workgroups will present on a community call in February to encourage participation

Community collaboration events:

- Symposia: Europe, APAC, Global
- Virtual events: DevCon, Phenotype Phebruary, Sisyphus Challenge
  - Let's help each other learn how to do network studies by doing a network study together!
    - Collaboratively identify an important research question
    - Collaboratively design the analysis
    - Collaboratively execute across the network
    - Collaboratively interpret results and disseminate findings

- External collaboration opportunities
  - We will actively monitor external collaboration opportunities and promote them on OHDSI.org and community calls
- Foundational pillars that should be focus areas for 2023
  - Standardized vocabularies: Increase transparency and maturity with vocabulary development and evaluation process
  - Standardized data network: Increase transparency and maturity of OHDSI data network
  - Standardized open-source tools: Increase adoption and ease-of-use of HADES packages and other OHDSI open-source analytic tools

The proposed OHDSI calendar for 2023



10 Jan 2023

Phenotype Phebruary 2023: How To Join The Effort

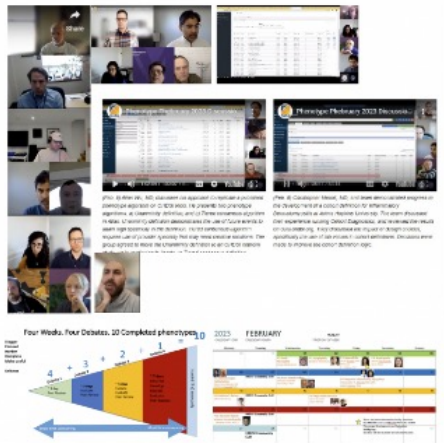
"Phenotype Phebruary" was a community-wide initiative to both develop and evaluate phenotypes for health outcomes that could be investigated by the community.

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

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

Sisyphus challenge: April - May

'System' required elements:
- Required phenotypes
- Analysis specifications
- Decision thresholds

Distributed data network, standardized to common data model

Network coordination

Data quality evaluation

Research question → Database diagnostics

Fail → STOP

Pass

Phenotype development and evaluation

Cohort definitions → Cohort diagnostics

Fail → STOP

Pass

Analysis reliability evaluation

Analysis design choices → Study diagnostics

Fail → STOP

Pass

Final unblinded results → Interface for exploration

Week 1: Study initiation


Week 0: Research questions

VEGF→ESRD

FQ→AA




MS biologics→PML

risankizumab→CVA

Sisyphus challenge: April - May

'System' required elements:
- Required phenotypes
- Analysis specifications
- Decision thresholds

Distributed data network, standardized to common data model

Network coordination

Data quality evaluation

Research question → Database diagnostics

Fail → STOP

Pass

Phenotype development and evaluation

Cohort definitions → Cohort diagnostics

Fail → STOP

Pass

Analysis reliability evaluation

Analysis design choices → Study diagnostics

Fail → STOP

Pass

Final unblinded results

Interface for exploration

Week 2: Data diagnostics

Sisyphus challenge: April - May

'System' required elements:
- Required phenotypes
- Analysis specifications
- Decision thresholds

Distributed data network, standardized to common data model

Network coordination

Data quality evaluation

Research question → Database diagnostics

Database diagnostics: Fail → STOP

Pass

Phenotype development and evaluation

Cohort definitions → Cohort diagnostics

Cohort diagnostics: Fail → STOP

Pass

Analysis reliability evaluation

Analysis design choices → Study diagnostics

Study diagnostics: Fail → STOP

Pass

Final unblinded results

Interface for exploration

Week 3-4: Phenotype development and evaluation

Sisyphus challenge: April - May

'System' required elements:
- Required phenotypes
- Analysis specifications
- Decision thresholds

Distributed data network, standardized to common data model

Network coordination

Data quality evaluation

Research question → Database diagnostics

Fail → STOP

Pass

Phenotype development and evaluation

Cohort definitions → Cohort diagnostics

Fail → STOP

Pass

Analysis reliability evaluation

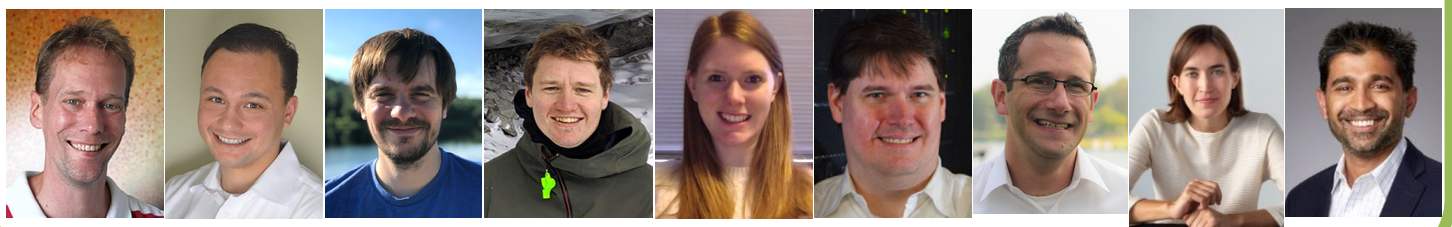
Analysis design choices → Study diagnostics

Fail → STOP

Pass

Final unblinded results → Interface for exploration

Only possible because of standardized analytics developed across our community



Week 5: Analysis design

Sisyphus challenge: April - May

'System' required elements:
- Required phenotypes
- Analysis specifications
- Decision thresholds

Distributed data network, standardized to common data model

Network coordination

Data quality evaluation

Research question → Database diagnostics

Database diagnostics → Pass

Database diagnostics → Fail → STOP

Phenotype development and evaluation

Cohort definitions → Cohort diagnostics

Cohort diagnostics → Pass

Cohort diagnostics → Fail → STOP

Analysis reliability evaluation

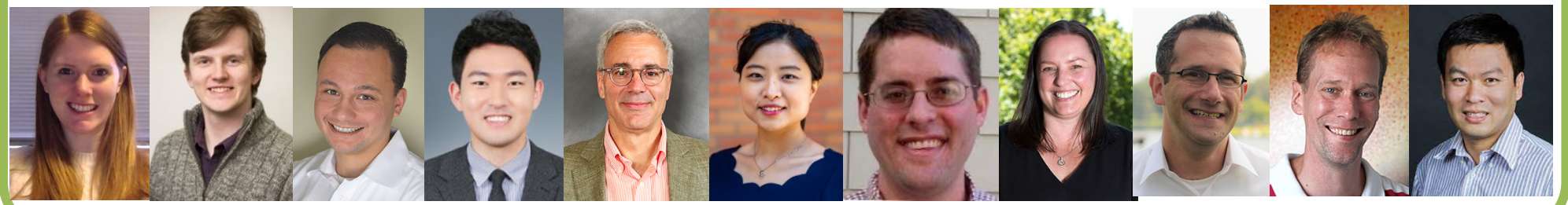
Analysis design choices → Study diagnostics

Study diagnostics → Pass

Study diagnostics → Fail → STOP

Final unblinded results → Interface for exploration

Week 6-8: Analysis execution, study diagnostics, evidence synthesis



Sisyphus challenge: April - May

'System' required elements:
- Required phenotypes
- Analysis specifications
- Decision thresholds

Distributed data network, standardized to common data model

Network coordination

Data quality evaluation

Research question → Database diagnostics

Fail → STOP

Pass

Phenotype development and evaluation

Cohort definitions → Cohort diagnostics

Fail → STOP

Pass

Analysis reliability evaluation

Analysis design choices → Study diagnostics

Fail → STOP

Pass

Final unblinded results → Interface for exploration

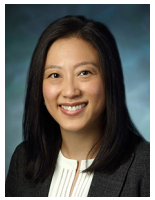
Week 9: Results interpretation

VEGF→ESRD

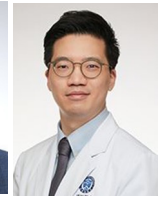
FQ→AA

MS biologics→PML

risankizumab→CVA





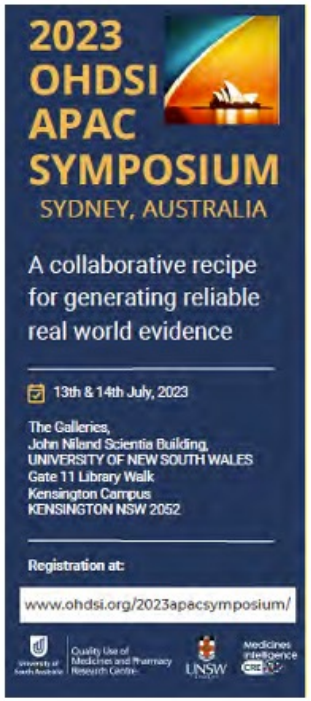


OHDSI Europe - June

The numbers

- 3 days
- 350 attendees
- 5 plenary sessions
- 10 rapid fire presentations
- 89 posters
- 7 national nodes
- 5 software demo's
- 2 blues brothers

OHDSI APAC - June



- **Two-day in-person event**
  - Symposium Day 1: Main Conference
  - Symposium Day 2: Tutorials + Oncology Workgroup discussions
- **110 attendees**
  - 58% Aus (*All Aus regions represented excl. NT*)
  - 42% international
    - 32% APAC (Korea, Taiwan, Japan, Singapore, Hong Kong, China)
    - 10% Other (US, UK & Sweden)
- **Diverse participant representation**
  - Academics, clinicians, students, regulators, industry, not-for-profit (Minderoo Foundation), OHDSI devotees & one consumer!
- **Eight Symposium sessions including**
  - 30 speakers
  - 12 speaker presentations including,
    - 7 lightning talks representing Asia-Pacific
    - 2 panel discussions
    - 6 tutorial presentations
    - **1 (Oncology) workgroup brain-storm session**
  - 21 poster presentations
- **One phenomenal APAC Steering Committee – thanks all!**
- … and AI-generated beer!

https://ohdsi.org/2023apacsymposium/

OHDSI Global - October

- >430 attendees over 3 days
- Collaborator showcase: 137 posters, 24 software demos, 10 lightning talks
- 18 workshops and HL7-OHDSI Connect-a-thon

https://www.ohdsi.org/ohdsi2023/

Standardized vocabularies: Increase transparency and maturity with vocabulary development and evaluation process

Landscape assessment

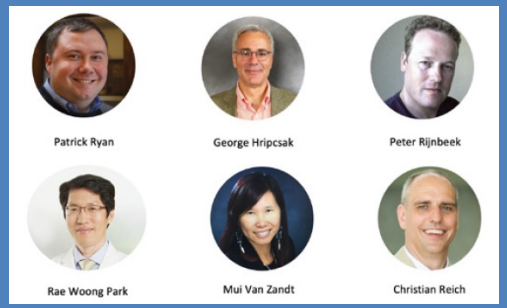
FINDINGS

- 87% of the community feels confident about Vocabularies' integrity
- Most commonly used vocabularies: SNOMED, ICD 9/10 (US and int versions), MedDRA, ICDO3, ATC, RxNorm/RxE, ICD10PCS, ICD9Proc, CPT4, LOINC, CVX, HCPCS, UCUM, NDC, NAACCR, Cancer Modifier
- Most update data annually or semi-annually

NEEDS

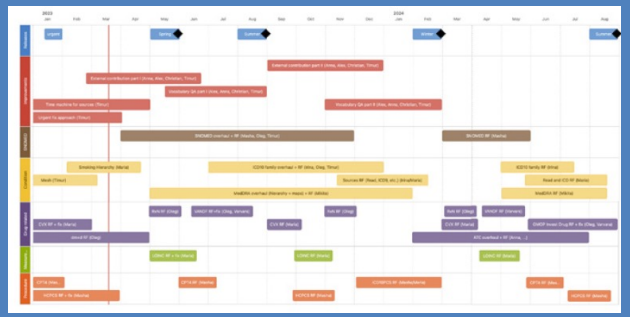
- Transparent release schedule
- Vocabulary changes, versioning
- Transparent QA/QC
- Better coverage and hierarchies
- More documentation and educational materials

Vocabulary committee

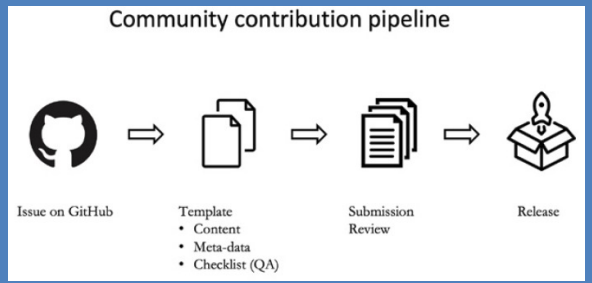


Vocabulary team

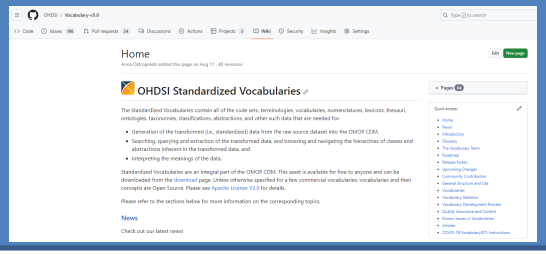
Release schedule and roadmap



Community contributions



Quality framework & documentation



Standardized data network: Increase transparency and maturity of OHDSI data network

OHDSI Evidence Network

OHDSI is proud to have a global community dedicated to generating real-world evidence and which recognizes the opportunity to collaborate together as part of a distributed network based on standardized data and standardized analytics.

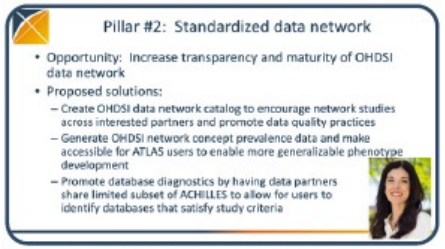
The OHDSI Evidence Network consists of organizations equipped with access to one or more databases standardized to the OMOP CDM who express a keen interest in participating in OHDSI network studies. Collaboratively, OHDSI Evidence Network partners share aggregate summary statistics about their databases, which are used to support Database Diagnostics, helping identify databases within the network that are fit-for-use for particular research questions. Additionally, partners have the opportunity to opt in and contribute to network studies proposed by the OHDSI community.

The recent SOS challenge serves as a compelling demonstration of the OHDSI Evidence Network's current capabilities and its promising future potential. We wholeheartedly encourage all organizations that are adopting the OMOP CDM and aspire to apply standardized analytics for the reliable generation of real-world evidence to become part of the OHDSI Evidence Network.

A message from Common Data Model workgroup lead Clair Blacketer ...

During the first community call of 2023, Patrick Ryan unveiled the strategic priorities for the OHDSI Community for the year. Among these, a key focus is on enhancing the transparency and maturity of the OHDSI network.

To address this objective, we began by considering how network studies are currently conducted, recognizing the challenges and complexities faced by collaborating organizations when contributing to the body of evidence. This investigation led to the creation of Database Diagnostics, a tool designed to answer a critical question: when tackling a specific research inquiry, which data sources within the OHDSI Evidence Network are the most relevant and suitable for generating robust evidence?



This innovative approach leverages aggregated summary statistics from each data source, obtained through the open-source tool dbProfile. It evaluates data fitness-for-use across various dimensions, including patient demographics, domain coverage, longitudinal data availability, and the capture of target, comparator, and outcome variables. The overarching vision was to establish these database profiles as the foundation to enable the OHDSI Evidence Network.

Organizations and Data Sources in the OHDSI Evidence Network

Ajou University • Ajou University
Casa di Cura Igea • Casa di Cura Igea
Clinical Center of Montenegro • Clinical Center of Montenegro
Columbia University Medical Center • Columbia University Medical Center
Hong Kong University • UK THIN
IQVIA • Australia EMR
IQVIA • Disease Analyzer France
IQVIA • Disease Analyzer Germany
IQVIA • Japan Claims
IQVIA • Japan HIS
IQVIA • Longitudinal Patient Database (LPD) in Belgium
IQVIA • Longitudinal Patient Database (LPD) in France
IQVIA • Longitudinal Patient Database (LPD) in Italy
IQVIA • Longitudinal Patient Database (LPD) in Spain
IQVIA • OMOP US Hospital Data Master
IQVIA • Pharmetrics Plus
IQVIA • UK Medical Research Data EMIS
IQVIA • UK Medical Research Data THIN
IQVIA • US Open Claims
Janssen Research & Development • JMDC
Janssen Research & Development • Merative® Marketscan® Commercial Claims and Encounters
Janssen Research & Development • Merative® Marketscan® Medicare Supplemental
Janssen Research & Development • Merative® Marketscan® Multi-State Medicaid
Janssen Research & Development • Optum's Clinformatics® Data Mart - Date of Death
Janssen Research & Development • Optum's Clinformatics® Data Mart - Socio-Economic Status
Janssen Research & Development • Optum's Longitudinal EHR Repository
Janssen Research & Development • Premier Healthcare Database
Johns Hopkins University • Johns Hopkins University
National University of Singapore • National University of Singapore
Northeastern • IQVIA Pharmetrics Plus
Organization Name • Data Source Name
Taipei Medical University • Taipei Medical University
Tufts University Medical Center • Tufts University Medical Center
University of Nebraska Medical Center • University of Nebraska Medical Center
University of Southern California • Keck Medical Center
US Department of Veteran's Affairs • US Department of Veteran's Affairs
Yinzhou Bigdata Platform • Yinzhou Bigdata Platform

On March 28, 2023, the OHDSI Global Community initiated the Save Our Sisyphus (SOS) Challenge, a groundbreaking opportunity for collaborative research involving simultaneous participation in four different network studies. What made it truly remarkable was that any organization interested in joining the OHDSI Evidence Network could contribute to these studies by sharing their database profiles for the data sources they had access to. These profiles were centrally aggregated at the OHDSI Central Coordinating Center, enabling us to empirically determine which of the four study questions each data source was best suited to address. This inaugural OHDSI Evidence Network endeavor encompassed 36 diverse adata sources from 16 different organizations. Not only did this foster rapid evidence generation and collaboration during the SOS Challenge, but it also positioned us for future collaborations on additional network studies as part of the OHDSI Evidence Network.

If you are interested in becoming a part of the OHDSI Evidence Network and contributing to advancing evidence-based healthcare, please use the provided QR code to complete a brief form about your organization and your data source. A member of the OHDSI Network Data Quality Working Group will reach out to you to explore this exciting opportunity further!

Join The OHDSI Evidence Network

Standardized open-source tools: Increase adoption and ease-of-use of HADES packages and other OHDSI open-source analytic tools

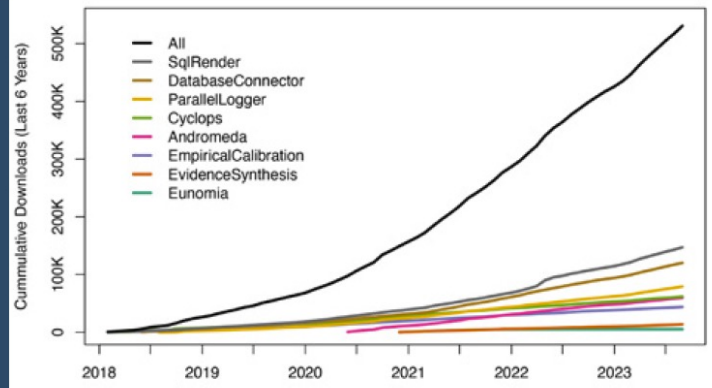
HADES

HADES is a set of open source R packages for large scale analytics, including population characterization, population-level causal effect estimation, and patient-level prediction.

The packages offer R functions that together can be used to perform an observational study through the full journey from data to evidence, including data manipulation, statistical modeling, and results generation with supporting statistics, tables and figures.

Each package includes functions for specifying and subsequently executing multiple analyses efficiently. HADES supports best practices for use of observational data as learned from previous and ongoing research, such as transparency, reproducibility, as well as measuring of the operating characteristics of methods in a particular context and subsequent empirical calibration of estimates produced by the methods.

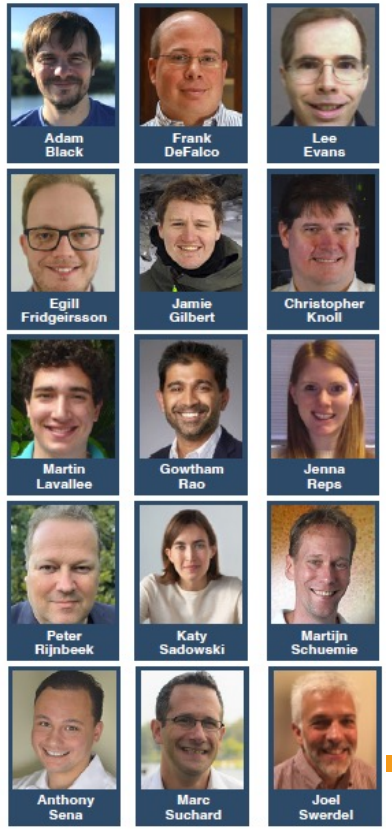
Learn more about the individual HADES packages in this section.



The eight HADES packages shown above have been released on CRAN and have been downloaded more than 500,000 times.

HADES Maintainers

The open-source tools that empower OHDSI research are not only available to the community, but they are DEVELOPED by the community. We thank the many developers and maintainers who empower our research initiatives around the world!



Package	Version	Maintainer(s)	Availability
Achilles	v1.7.2	Frank DeFalco	CRAN
Andromeda	v0.6.3	Adam Black	CRAN
BigKnn	v1.0.2	Martijn Schuemie	GitHub
BrokenAdaptiveRidge	v1.0.0	Marc Suchard	CRAN
Capr	v2.0.7	Martin Lavallee	GitHub
Characterization	v0.1.2	Jenna Reps	GitHub
CirceR	v1.3.1	Chris Knoll	GitHub
CohortDiagnostics	v3.2.4	Jamie Gilbert	GitHub
CohortExplorer	v0.0.17	Gowtham Rao	CRAN
CohortGenerator	v0.8.0	Anthony Sena	GitHub
CohortMethod	v5.1.0	Martijn Schuemie	GitHub
Cyclops	v3.3.1	Marc Suchard	CRAN
DatabaseConnector	v6.2.4	Martijn Schuemie	CRAN
DataQualityDashboard	v2.4.0	Katy Sadowksi	GitHub
DeepPatientLevelPrediction	v2.0.0	Egill Fridgeirsson	GitHub
EmpiricalCalibration	v3.1.1	Martijn Schuemie	CRAN
EnsemblePatientLevelPrediction	v1.0.2	Jenna Reps	GitHub
Eunomia	v1.0.2	Frank DeFalco	GitHub
EvidenceSynthesis	v0.5.0	Martijn Schuemie	CRAN
FeatureExtraction	v3.3.1	Anthony Sena	GitHub
Hydra	v0.4.0	Anthony Sena	GitHub
IterativeHardThresholding	v1.0.2	Marc Suchard	CRAN
MethodEvaluation	v2.3.0	Martijn Schuemie	GitHub
OhdsiSharing	v0.2.2	Lee Evans	GitHub
OhdsiShinyModules	v2.0.0	Jenna Reps	GitHub
ParallelLogger	v3.3.0	Martijn Schuemie	CRAN
PatientLevelPrediction	v6.3.5	Jenna Reps & Peter Rijnbeek	GitHub
PhenotypeLibrary	v3.25.0	Gowtham Rao	GitHub
PheValuator	v2.2.10	Joel Swerdel	GitHub
ResultModelManager	v0.5.1	Jamie Gilbert	GitHub
ROhdsiWebApi	v1.3.3	Gowtham Rao	GitHub
SelfControlledCaseSeries	v4.2.0	Martijn Schuemie	GitHub
SelfControlledCohort	v1.6.0	Jamie Gilbert	GitHub
ShinyAppBuilder	v1.1.2	Jenna Reps	GitHub
SqlRender	v1.16.1	Martijn Schuemie	CRAN

Other highlights in 2023

- 100 publications
  - Including Faaizah Arshad's first OHDSI lead-authored publication
  - OHDSI's largest network study (26 databases), led by Erica Voss
  - FDA-BEST work developing Bayesian framework for vaccine safety surveillance, led by Fan Bu
- PhDs with OHDSI research as part of their dissertation
  - Anna Ostropolets, Linying Zhang, Ross Williams, Alex Rekkas, Chungsoo Kim
- 8 new Titans
  - Nicole Pratt, Gyeol Song, Cynthia Sung, Gowtham Rao, Azza Shoaibi, Jessie Tong, Katy Sadowski, Center for Surgical Sciences

Join by Web **PollEv.com/patrickryan800**

What was your favorite OHDSI highlight in 2023?

Nobody has responded yet.

Hang tight! Responses are coming in.

Happy Birthday OHDSI!
10 years in review

Join by Web **PollEv.com/patrickryan800**

What was your favorite OHDSI highlight over the last 10 years?

Nobody has responded yet.

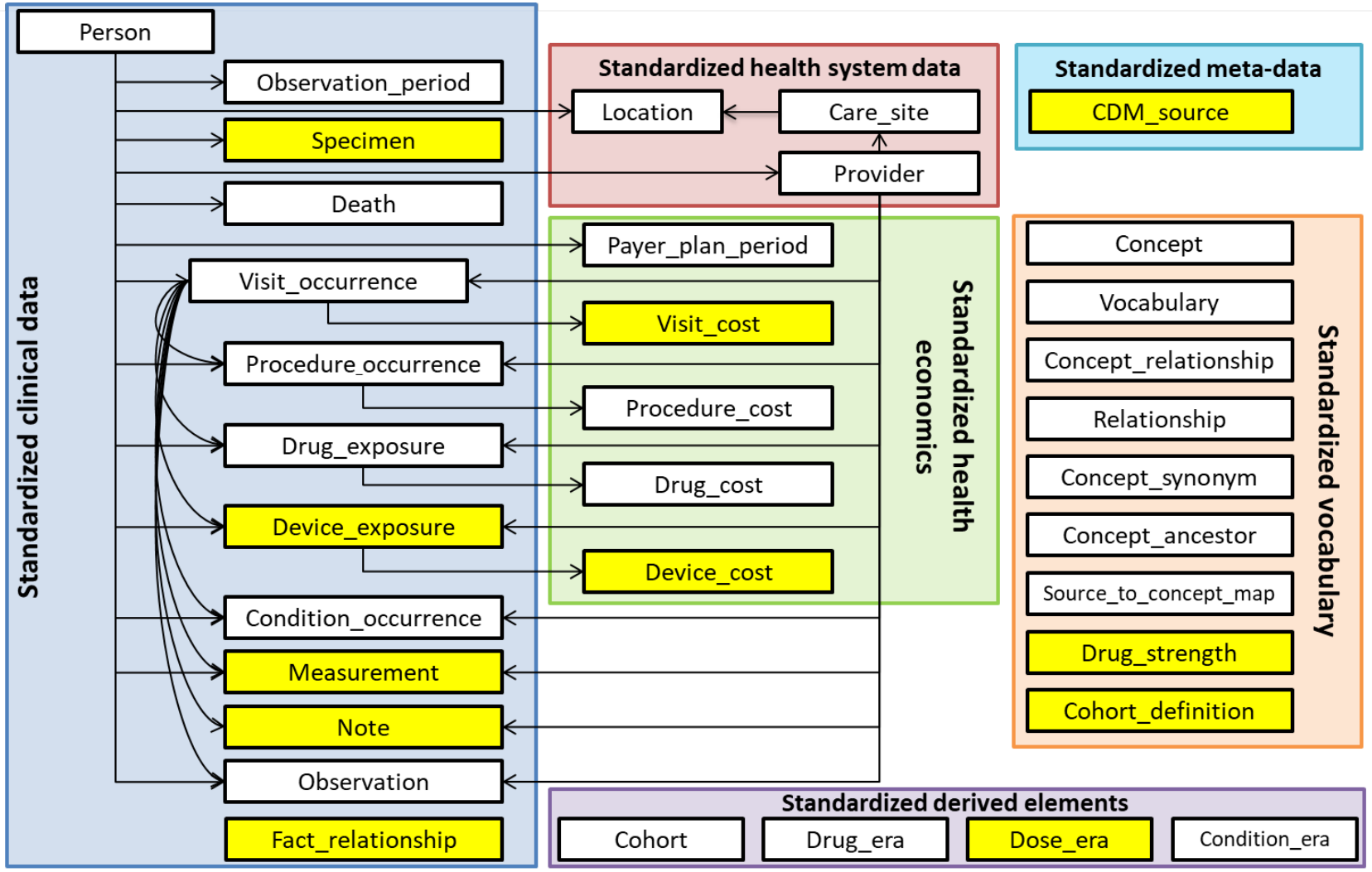
Hang tight! Responses are coming in.

On 16 December 2013, Columbia University Department of Biomedical Informatics formally voted to establish the OHDSI Central Coordinating Center

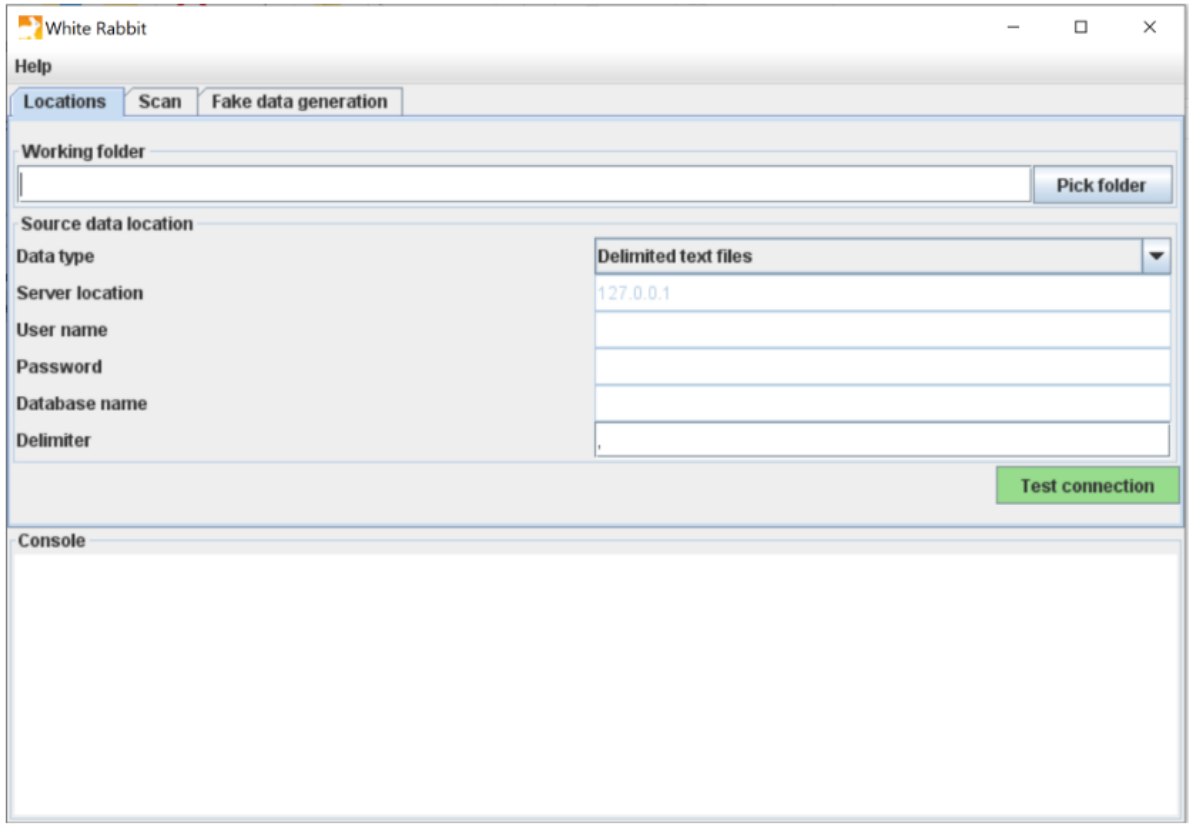
…and what a journey it has been ever since….

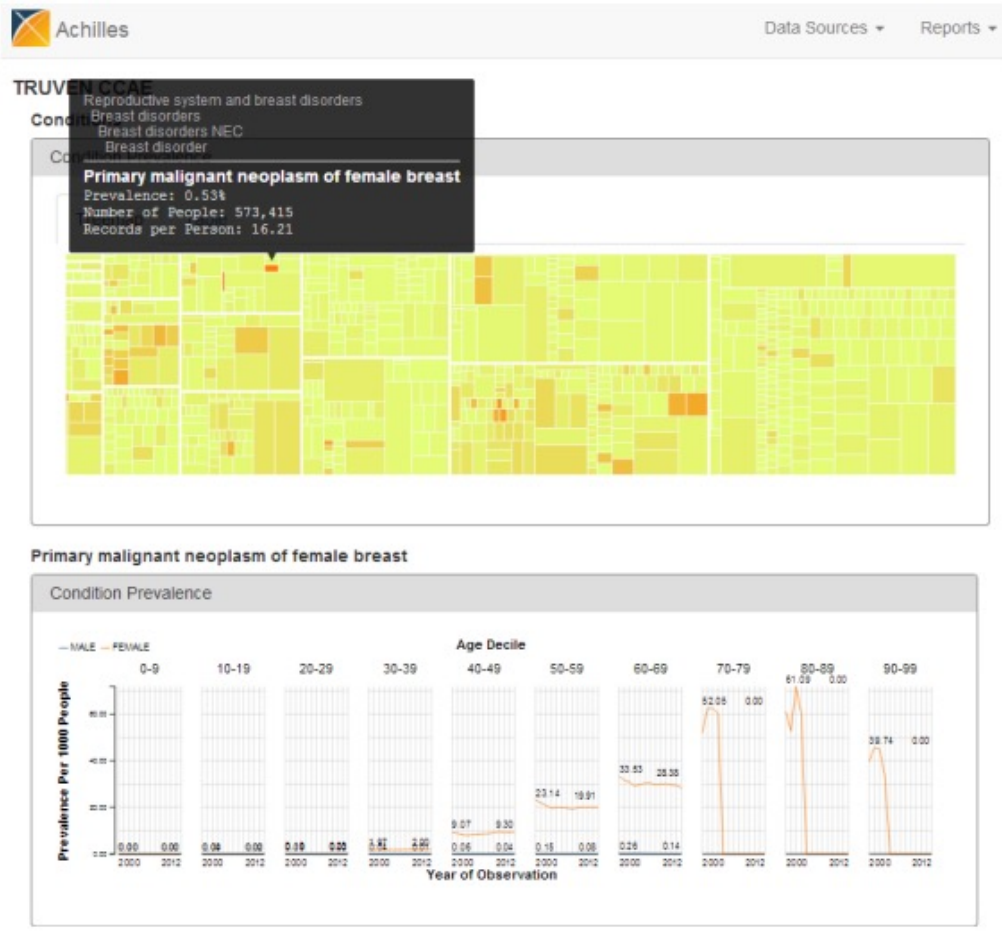
First OHDSI release of OMOP CDM (2014)

OMOP Common Data Model v5 - What's new from v4 (yellow)?



First open-source tool releases (2014)





First OHDSI F2F (2014)

First OHDSI community paper (2015)

MEDINFO 2015: eHealth-enabled Health
I.N. Sarkar et al. (Eds.)
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doi:10.3233/978-1-61499-564-7-574

Observational Health Data Sciences and Informatics (OHDSI): Opportunities for Observational Researchers

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[m] College of Medical Science and Technology (CoMST), Taipei Medical University, Taipei, Taiwan
[n] Department of Statistics, Columbia University, New York, NY, USA

1,032 citations!

First OHDSI community paper (2015)

574

MEDINFO 2015: eHealth-enabled Health
I.N. Sarkar et al. (Eds.)
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Observational Health Data Sciences and Informatics (OHDSI): Opportunities for Observational Researchers

George Hripcsak[a], Jon D. Duke[b], Nigam H. Shah[c], Christian G. Reich[d], Vojtech Huser[e], Martijn J. Schuemie[f,g], Marc A. Suchard[h], Rae Woong Park[i], Ian Chi Kei Wong[f], Peter R. Rijnbeek[j], Johan van der Lei[j], Nicole Pratt[k], G. Niklas Norén[l], Yu-Chuan Li[m], Paul E. Stang[g], David Madigan[n], Patrick B. Ryan[g]

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[b] Regenstrief Institute, Indianapolis, IN, USA
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[k] School of Pharmacy and Medical Sciences, University of South Australia, Australia
[l] Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, Uppsala, Sweden
[m] College of Medical Science and Technology (CoMST), Taipei Medical University, Taipei, Taiwan
[n] Department of Statistics, Columbia University, New York, NY, USA

Table 1. Tables in the OMOP Common Data Model V5.0

Model Domain	Table Names
Standardized Clinical Data Tables	PERSON, OBSERVATION_PERIOD, SPECIMEN, DEATH, VISIT_OCCURRENCE, PROCEDURE_OCCURRENCE, DRUG_EXPOSURE, DEVICE_EXPOSURE, CONDITION_OCCURRENCE, MEASUREMENT, NOTE, OBSERVATION, FACT_RELATIONSHIP
Standardized Health System Data Tables	LOCATION, CARE_SITE, PROVIDER
Standardized Health Economics Data Tables	PAYER_PLAN_PERIOD, VISIT_COST, PROCEDURE_COST, DRUG_COST, DEVICE_COST
Standardized Derived Elements	COHORT, COHORT_ATTRIBUTE, DRUG_ERA, DOSE_ERA, CONDITION_ERA

The group's guiding principles are that the effort be:

1. Evidence-based, such that OHDSI's scientific research and development are driven by objective, empirical evidence to ensure accuracy and reliability;
2. Practical, going beyond methodological research, but developing applied solutions and generating clinical evidence;
3. Comprehensive, aiming to generate reliable scientific evidence for all interventions and all outcomes;
4. Transparent, such that all work products within OHDSI are Open Source and publicly available, including source code, analysis results, and other evidence generated in all our activities;
5. Inclusive, encouraging active participation from all stakeholders – patients, providers, payers, government, industry, academia – in all phases of research and development; and finally
6. Secure, protecting patient privacy and respecting data

"Over 90 participants from around the world have joined the collaborative with a vision to access a network of one billion patients to generate evidence about all aspects of healthcare, where patients, clinicians and all other decision-makers around the world use OHDSI tools and evidence every day."

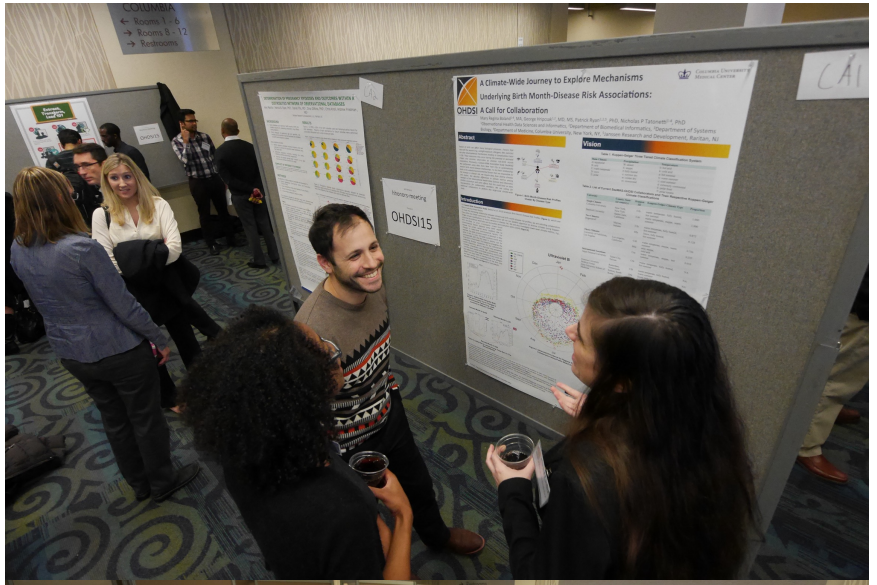
2014 survey:

- 58 databases using OMOP CDM
- >200 million unique patient records
- "it is feasible to impose a strong information model …represent a significant fraction of the world's population"

Software tools:

- ACHILLES for database characterization
- HERMES for vocabulary exploration
- PLATO for predictive modeling
- HERACLES for cohort characterization
- HOMER for causal inference

First OHDSI Global Symposium (2015)



First OHDSI network study (2016)

PNAS

CrossMark
click for updates

COLLOQUIUM PAPER

Characterizing treatment pathways at scale using the OHDSI network

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

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

- 11 databases in 4 countries
- 250 million patient records

First OHDSI network study (2016)

PNAS

Characterizing treatment pathways at scale using the OHDSI network

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

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

COLLOQUIUM PAPER

- Database-level heterogeneity: population, geography, health system policies
- Person-level heterogeneity: 10% of diabetes, 24% of hypertension, 11% of depression followed a unique treatment pathway

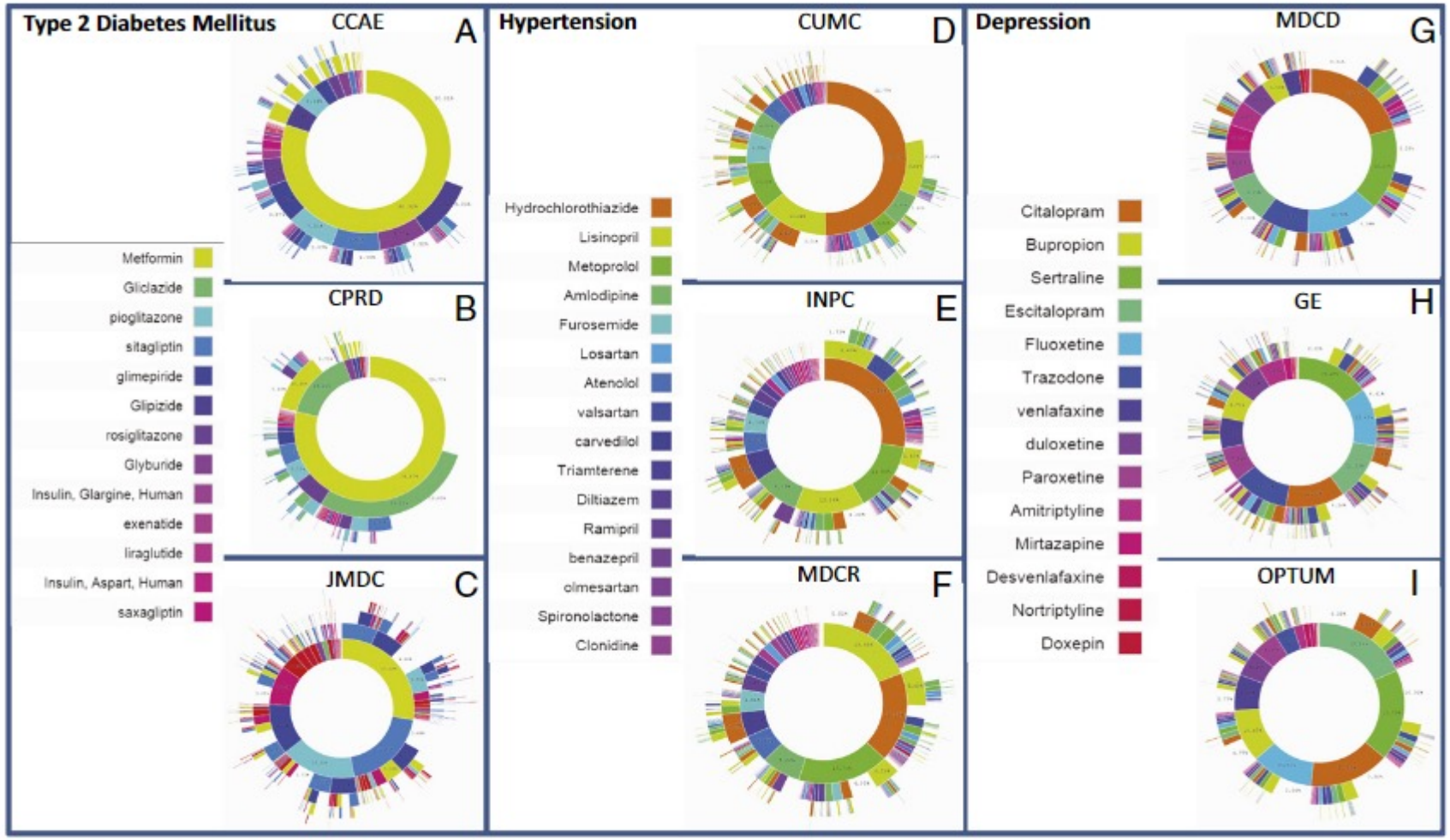


Fig. 3. For each disease, diabetes (*A–C*), hypertension (*D–F*), and depression (*G–I*), the inner circle shows the first relevant medication that the patient took, the second circle shows the second medication, and so forth. Three data sources are shown for each disease; the data source abbreviations are defined in Table 2.

First OHDSI methods research on estimation (2017)

PNAS

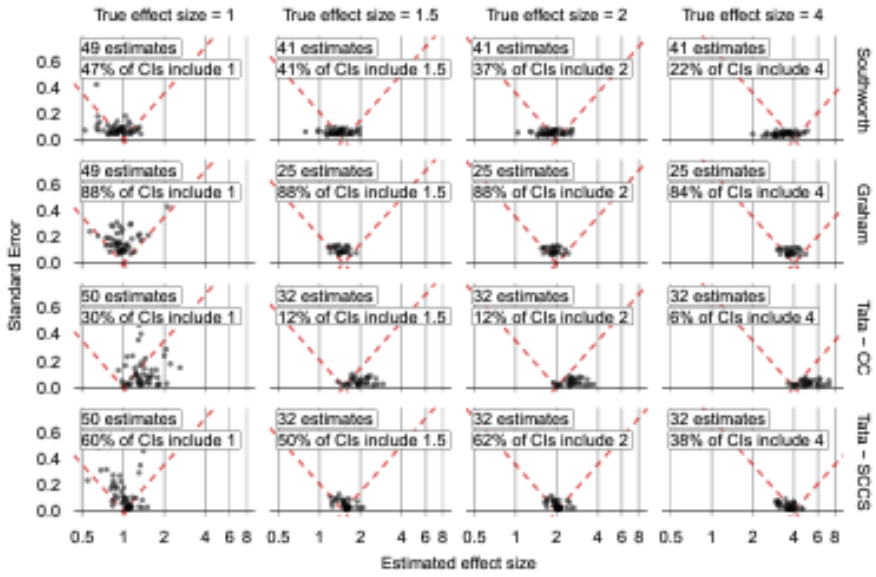
COLLOQUIUM PAPER

Empirical confidence interval calibration for population-level effect estimation studies in observational healthcare data

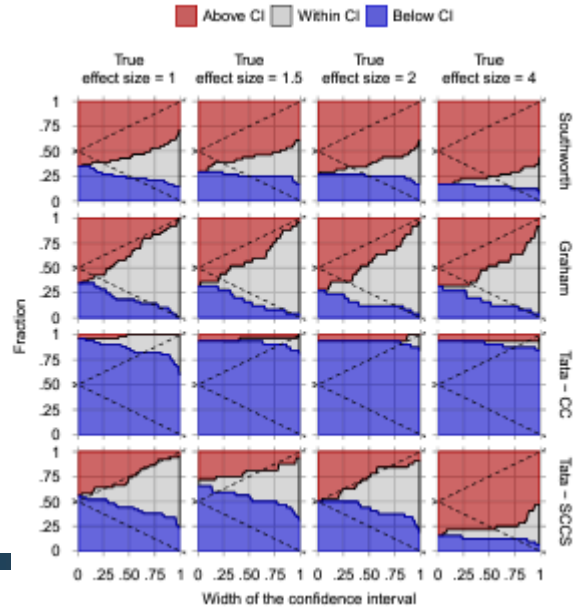
Martijn J. Schuemie[a,b,1], George Hripcsak[a,c,d], Patrick B. Ryan[a,b,c], David Madigan[a,e], and Marc A. Suchard[a,f,g,h]

[a]Observational Health Data Sciences and Informatics, New York, NY 10032; [b]Epidemiology Analytics, Janssen Research & Development, Titusville, NJ 08560; [c]Department of Biomedical Informatics, Columbia University, New York, NY 10032; [d]Medical Informatics Services, New York–Presbyterian Hospital, New York, NY 10032; [e]Department of Statistics, Columbia University, New York, NY 10027; [f]Department of Biomathematics, University of California, Los Angeles, CA 90095; [g]Department of Biostatistics, University of California, Los Angeles, CA 90095; and [h]Department of Human Genetics, University of California, Los Angeles, CA 90095

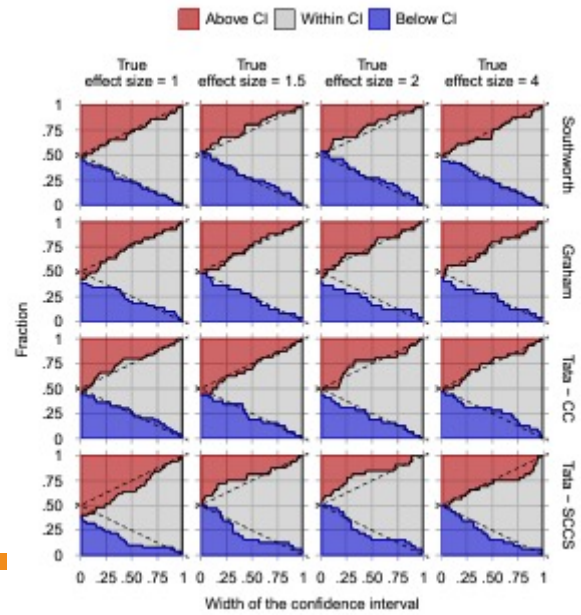
A sample of negative control experiments is needed to quantify bias



Before calibration:
CI can't be trusted



After calibration:
CI have appropriate coverage



First OHDSI regional symposia (2017-2018)

South Korea

Netherlands

China

First OHDSI methods research on prediction (2018)

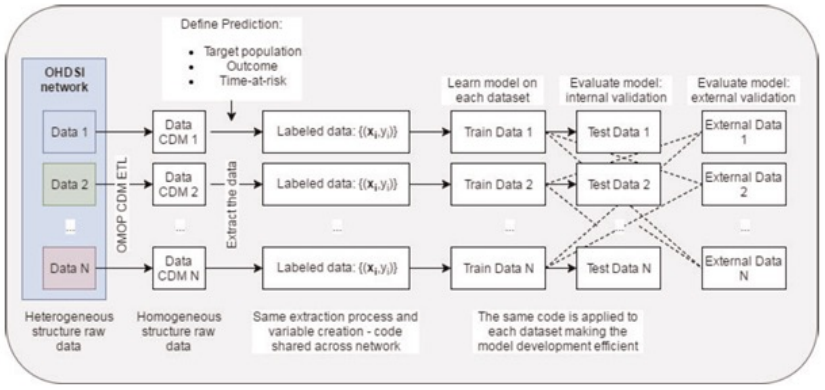
Journal of the American Medical Informatics Association, 25(8), 2018, 969–975
doi: 10.1093/jamia/ocy032
Advance Access Publication Date: 27 April 2018
Research and Applications

Research and Applications

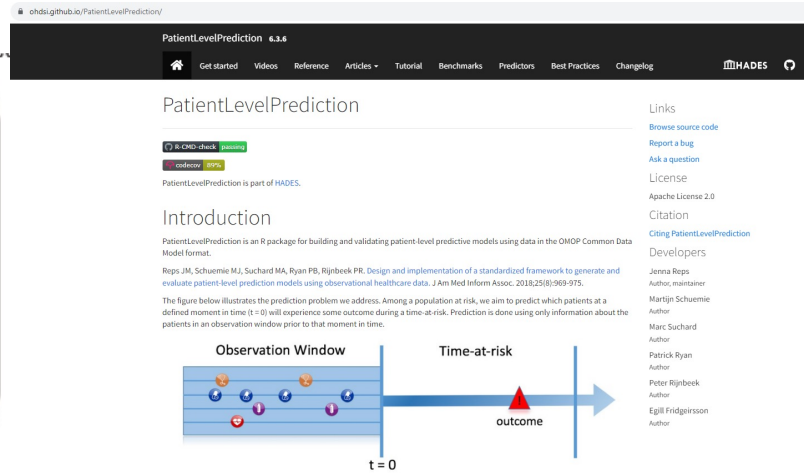
Design and implementation of a standardized framework to generate and evaluate patient-level prediction models using observational healthcare data

Jenna M Reps,[1] Martijn J Schuemie,[1] Marc A Suchard,[2] Patrick B Ryan,[1] and Peter R Rijnbeek[3]

Standardized Framework:



Open-source implementation:



Application at scale:

	Discrimination (AUC)				Calibration							
	CCAE	OPTUM	MDCR	MDCD	CCAE		OPTUM		MDCR		MDCD	
					Intercept	Slope	Intercept	Slope	Intercept	Slope	Intercept	Slope
Open-angle glaucoma	0.817	0.822	0.710	0.624	0.000	1.051	0.000	0.990	−0.001	1.495	0.000	1.399
Gastrointestinal hemorrhage	0.824	0.797	0.677	0.754	0.000	0.868	0.000	1.009	−0.001	0.952	0.000	0.633
Acute myocardial infarction	0.863	0.808	0.697	0.787	0.000	1.048	0.000	0.916	−0.003	1.404	0.000	1.263
Stroke	0.797	0.813	0.661	0.803	0.000	0.783	0.000	0.750	0.001	0.833	0.000	1.082
Suicide and suicidal ideation	0.796	0.805	0.690	0.710	0.002	1.711	−0.002	1.720	0.006	1.387	−0.002	1.773
Insomnia	0.683	0.667	0.672	0.636	0.023	1.314	0.010	1.305	0.029	1.379	0.025	1.109
Diarrhea	0.682	0.674	0.636	0.680	0.012	1.095	0.005	1.116	0.023	1.083	0.009	1.253
Nausea	0.701	0.675	0.651	0.668	0.021	1.111	0.015	1.099	0.034	0.999	0.036	1.152
Hypothyroidism	0.842	0.792	0.839	0.763	−0.002	1.343	0.000	1.051	0.002	1.557	−0.001	1.261
Constipation	0.704	0.705	0.651	0.645	0.010	1.132	0.005	1.238	0.027	1.080	0.010	1.268
Seizure	0.753	0.757	0.649	0.696	0.000	1.216	0.000	0.984	−0.001	1.212	0.001	1.107
Delirium	0.782	0.781	0.702	0.664	0.000	0.998	0.001	0.733	0.001	0.855	0.002	0.830
Alopecia	0.692	0.672	0.684	0.625	0.002	1.293	−0.001	1.323	−0.001	2.568	0.001	1.244
Tinnitus	0.696	0.672	0.576	0.638	0.003	1.152	−0.001	1.368	0.006	1.372	0.002	1.292
Vertigo	0.714	0.705	0.619	0.679	0.002	1.214	0.000	1.229	0.006	1.251	0.002	1.242
Hyponatremia	0.808	0.809	0.690	0.795	0.001	1.073	0.001	1.141	0.002	1.298	0.002	1.137
Decreased libido	0.710	0.738	0.662	0.627	0.002	1.179	0.000	1.684	−0.002	5.095	0.001	0.893
Fracture	0.674	0.734	0.679	0.657	0.001	1.037	0.001	1.119	0.007	1.019	−0.002	1.553
Hypotension	0.761	0.793	0.709	0.749	0.003	1.112	0.002	1.116	0.011	1.195	0.004	1.191
Acute liver injury	0.703	0.743	0.516	0.534	0.000	0.998	0.000	0.919	−0.003	5.698	0.001	−0.036
Ventricular arrhythmia and sudden cardiac death	0.776	0.806	0.732	0.808	0.000	0.857	0.000	1.034	0.000	0.806	−0.001	1.105

First OHDSI study-a-thon (2018)

First Women of OHDSI Real-World Analytics Leadership Forum (2019)

Book of OHDSI (2019)

First LEGEND-Hypertension study (2019)

Articles

THE LANCET

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

Lancet 2019; 394: 1816–26

Published Online October 24, 2019 https://doi.org/10.1016/S0140-6736(19)32317-7

See Comment page 1782

Department of Biostatistics, Fielding School of Public Health (Prof M A Suchard MD, M J Schuemie PhD), and Department of Biomathematics, David Geffen School of Medicine at UCLA (Prof M A Suchard), University of California, Los Angeles, CA, USA; Epidemiology Analytics, Janssen Research & Development, Titusville, NJ, USA (M J Schuemie, P B Ryan PhD); Department of Medicine, Yale University School of Medicine, New Haven, CA, USA (Prof H M Krumholz MD); Department of Biomedical Informatics, Ajou University School of Medicine, Suwon, South Korea (S C You MD); Department of Medicine, Weill Cornell Medical College, New York, NY, USA (R Chen MD); Department of Biomedical Informatics,

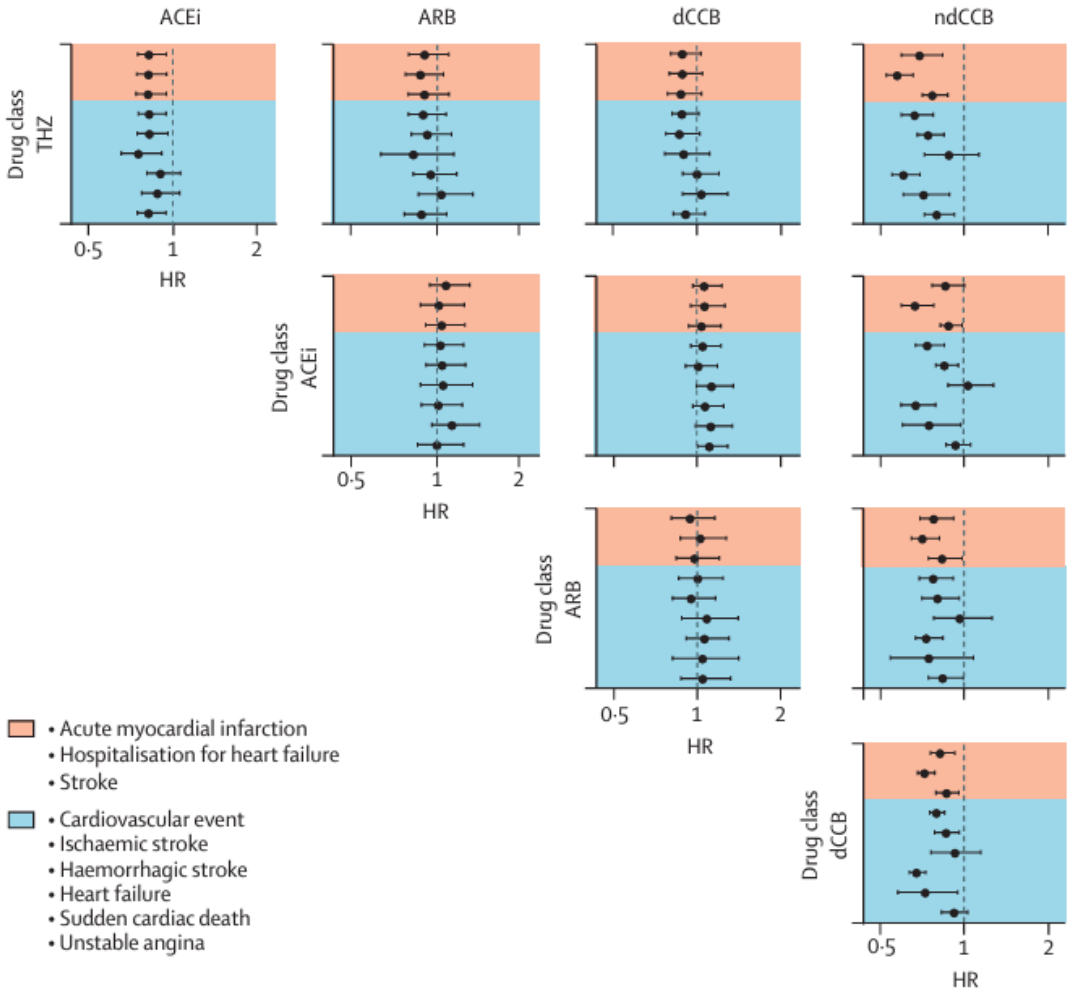
Summary

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 enzyme inhibitors, angiotensin receptor blockers, dihydropyridine calcium channel blockers, and non-dihydropyridine calcium channel blockers, in the absence of comorbid indications. Randomised trials have not further refined this choice.

Methods We developed a comprehensive framework for real-world evidence that enables comparative effectiveness and safety evaluation across many drugs and outcomes from observational data encompassing millions of patients, while minimising inherent bias. Using this framework, we did a systematic, large-scale study under a new-user cohort design to estimate the relative risks of three primary (acute myocardial infarction, hospitalisation for heart failure, and stroke) and six secondary effectiveness and 46 safety outcomes comparing all first-line classes across a global network of six administrative claims and three electronic health record databases. The framework addressed residual confounding, publication bias, and p-hacking using large-scale propensity adjustment, a large set of control outcomes, and full disclosure of hypotheses tested.

Findings Using 4·9 million patients, we generated 22 000 calibrated, propensity-score-adjusted hazard ratios (HRs) comparing all classes and outcomes across databases. Most estimates revealed no effectiveness differences between classes; however, thiazide or thiazide-like diuretics showed better primary effectiveness than angiotensin-converting enzyme inhibitors: acute myocardial infarction (HR 0·84, 95% CI 0·75–0·95), hospitalisation for heart failure (0·83, 0·74–0·95), and stroke (0·83, 0·74–0·95) risk while on initial treatment. Safety profiles also favoured thiazide or thiazide-like diuretics over angiotensin-converting enzyme inhibitors. The non-dihydropyridine calcium channel blockers were significantly inferior to the other four classes.

Interpretation This comprehensive framework introduces a new way of doing observational health-care science at scale. The approach supports equivalence between drug classes for initiating monotherapy for hypertension—in keeping with current guidelines, with the exception of thiazide or thiazide-like diuretics superiority to angiotensin-converting enzyme inhibitors and the inferiority of non-dihydropyridine calcium channel blockers.

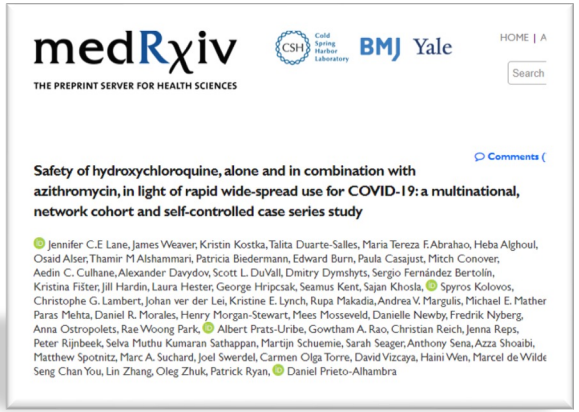


First virtual study-a-thon (2020)

COVID impact: Estimating the safety of hydroxychloroquine (2020)

- 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.



COVID impact: Characterizing background rates of adverse events for vaccine surveillance (2021)

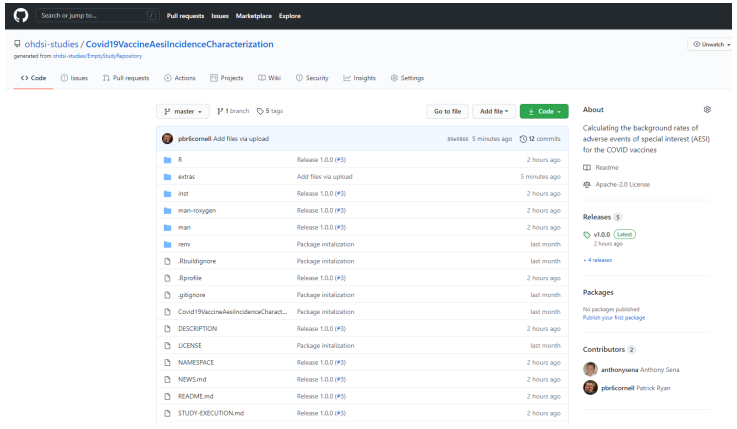
FDA U.S. FOOD & DRUG ADMINISTRATION

Center for Biologics Evaluation and Research
Office of Biostatistics and Epidemiology

CBER Surveillance Program

COVID-19 Vaccine Safety Surveillance: Active Monitoring Master Protocol

February 10, 2021



thebmj

RESEARCH: SPECIAL PAPER

OPEN ACCESS

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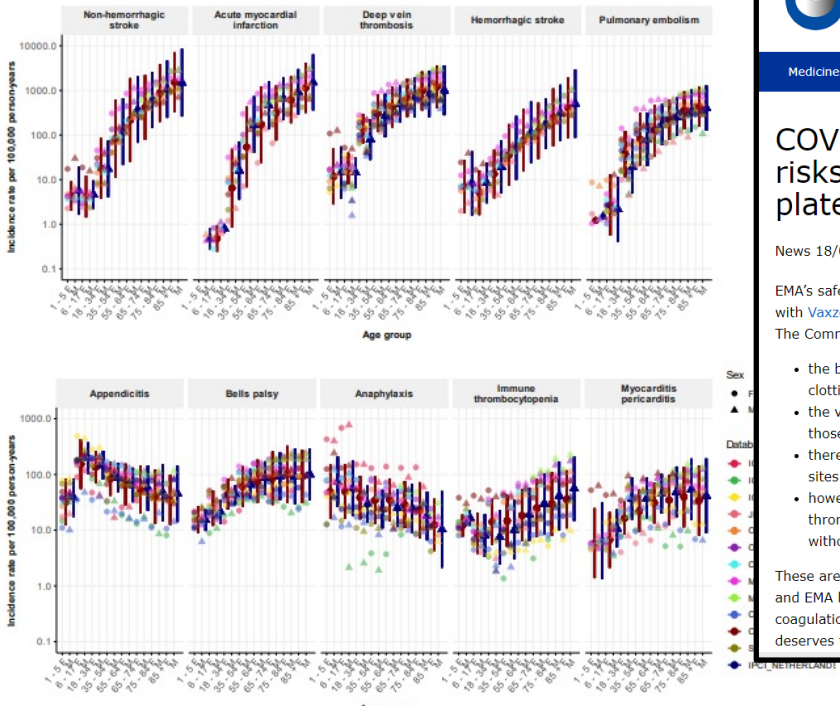
FAST TRACK

Characterising the background incidence rates of adverse events of special interest for covid-19 vaccines in eight countries: multinational network cohort study

Xintong Li,[1] Anna Ostropolets,[2] Rupa Makadia,[3] Azza Shoaibi,[3] Gowtham Rao,[3] Anthony G Sena,[3,6] Eugenia Martinez-Hernandez,[4] Antonella Delmestri,[1] Katia Verhamme,[6,7] Peter R Rijnbeek,[6] Talita Duarte-Salles,[5] Marc A Suchard,[8,9] Patrick B Ryan,[2,3] George Hripcsak,[2] Daniel Prieto-Alhambra[1,6]

Figure 1: Age-sex stratified incidence rates, overall and per database, for 15 adverse events of special interest



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COVID-19 Vaccine AstraZeneca: benefits still outweigh the risks despite possible link to rare blood clots with low blood platelets

Share

News 18/03/2021

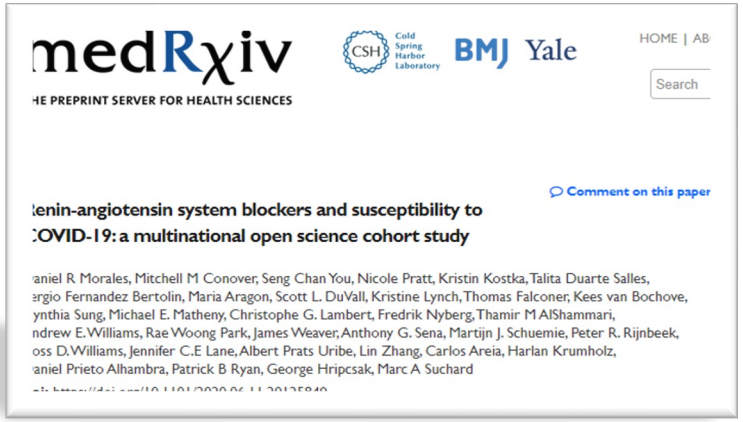
EMA's safety committee, PRAC, concluded its preliminary review of a signal of blood clots in people vaccinated with Vaxzevria (previously COVID-19 Vaccine AstraZeneca) at its extraordinary meeting of 18 March 2021. The Committee confirmed that:

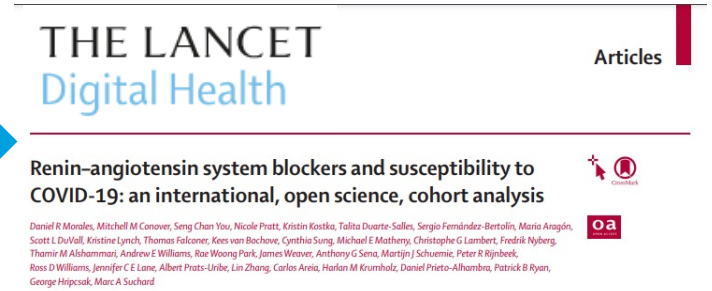
- the benefits of the vaccine in combating the still widespread threat of COVID-19 (which itself results in clotting problems and may be fatal) continue to outweigh the risk of side effects;
- the vaccine is not associated with an increase in the overall risk of blood clots (thromboembolic events) in those who receive it;
- there is no evidence of a problem related to specific batches of the vaccine or to particular manufacturing sites;
- however, the vaccine may be associated with very rare cases of blood clots associated with thrombocytopenia, i.e. low levels of blood platelets (elements in the blood that help it to clot) with or without bleeding, including rare cases of clots in the vessels draining blood from the brain (CVST).

These are rare cases – around 20 million people in the UK and EEA had received the vaccine as of March 16 and EMA had reviewed only 7 cases of blood clots in multiple blood vessels (disseminated intravascular coagulation, DIC) and 18 cases of CVST. A causal link with the vaccine is not proven, but is possible and deserves further analysis.

COVID impact: Increasing the reliability of the research process (2021)

- 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.

A consistent commitment to reliable evidence: Plenary sessions at OHDSI symposia

2015 - OHDSI in Action: Open-source analytics for patient-centered evidence

2016- OHDSI's journey toward reliable evidence generation and dissemination

2017 - Journey Through Clinical Characterization: Large-scale honest incidence

2018 - Large-scale Evidence Generation and Evaluation of Network of Databases (LEGEND): Clinical applications in hypertension

2019 - A journey toward real-world evidence for regulatory decision-making:

- Building confidence in real-world data - Data quality reporting
- Establishing scientific best practices for real-world analysis - Book Of OHDSI
- Proving reliable real-world evidence - Replicating RCTs using LEGEND

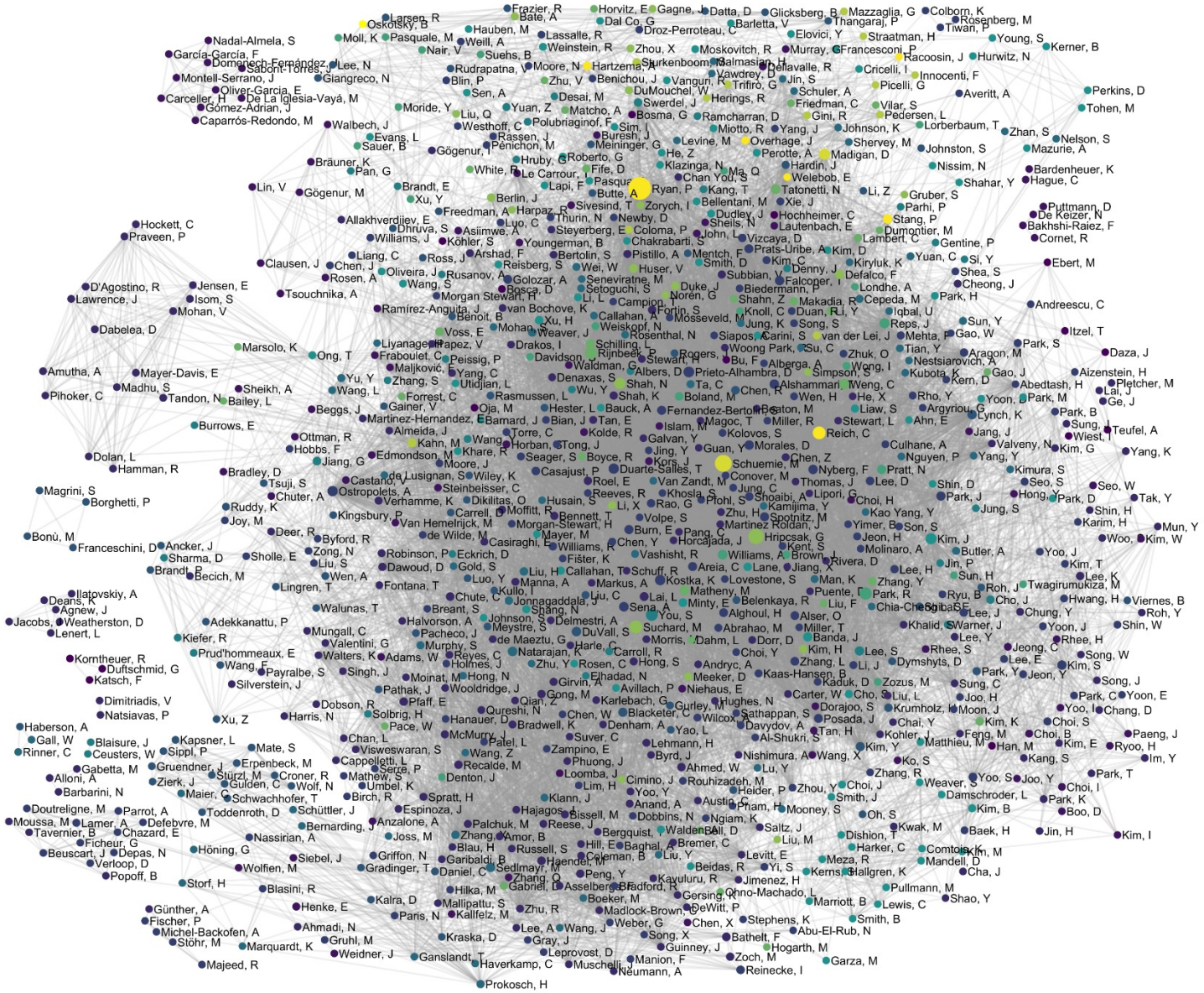
2020 – The Journey to Reliable Evidence: Reproducibility and Generalizability

2021 - Large Scale Network Phenotype Development, Evaluation and Characterization

2022 – Objective Diagnostics: A pathway to provably reliable evidence

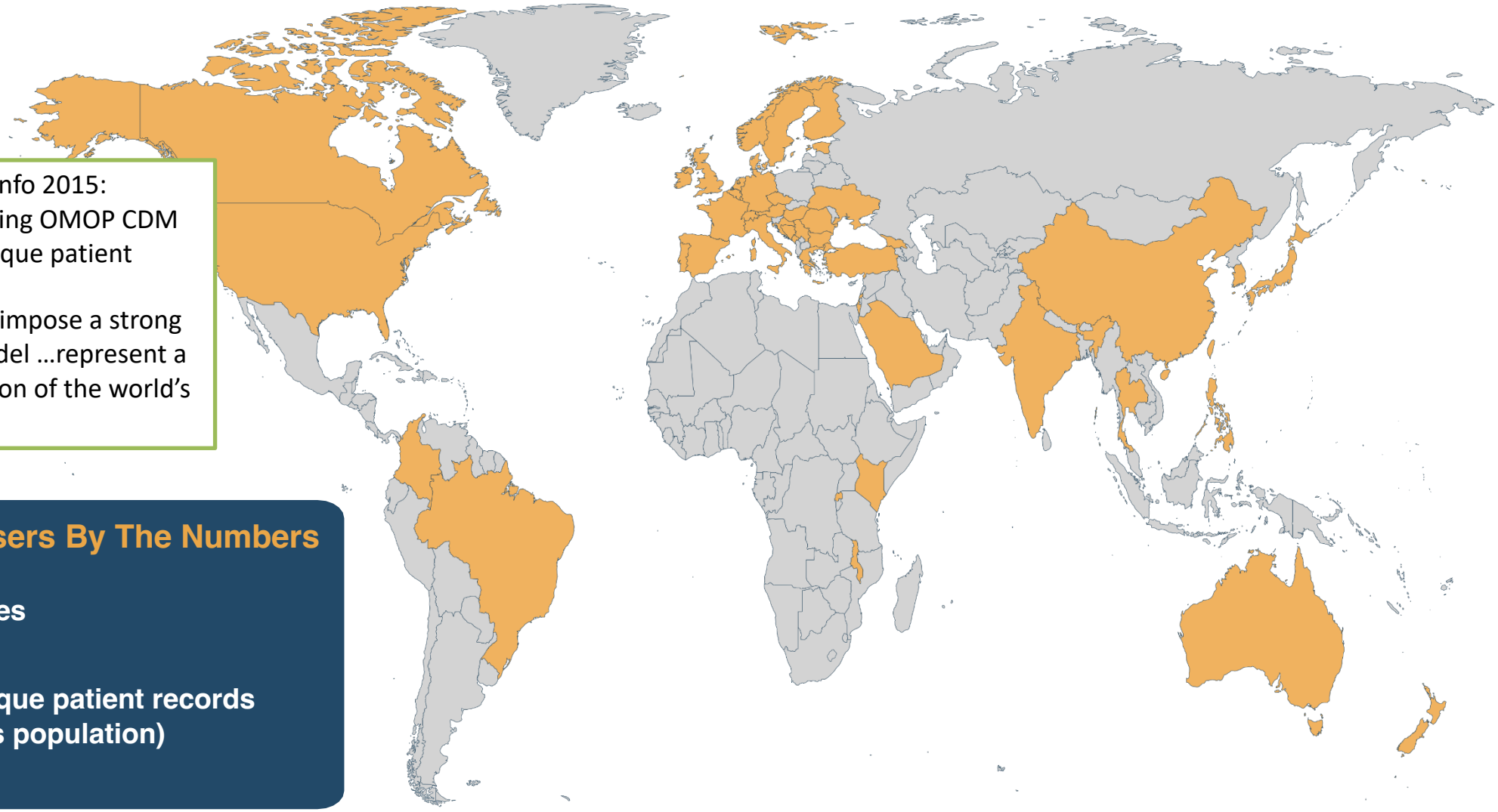
2023 – Improving the reliability and scale of case validation.

OHDSI collaborations in scholarship (2013-2023)



- >620 publications
- >3,600 authors
- >12,000 citations

OMOP Common Data Model adoption (2023)



Hripcsak et al, MedInfo 2015:

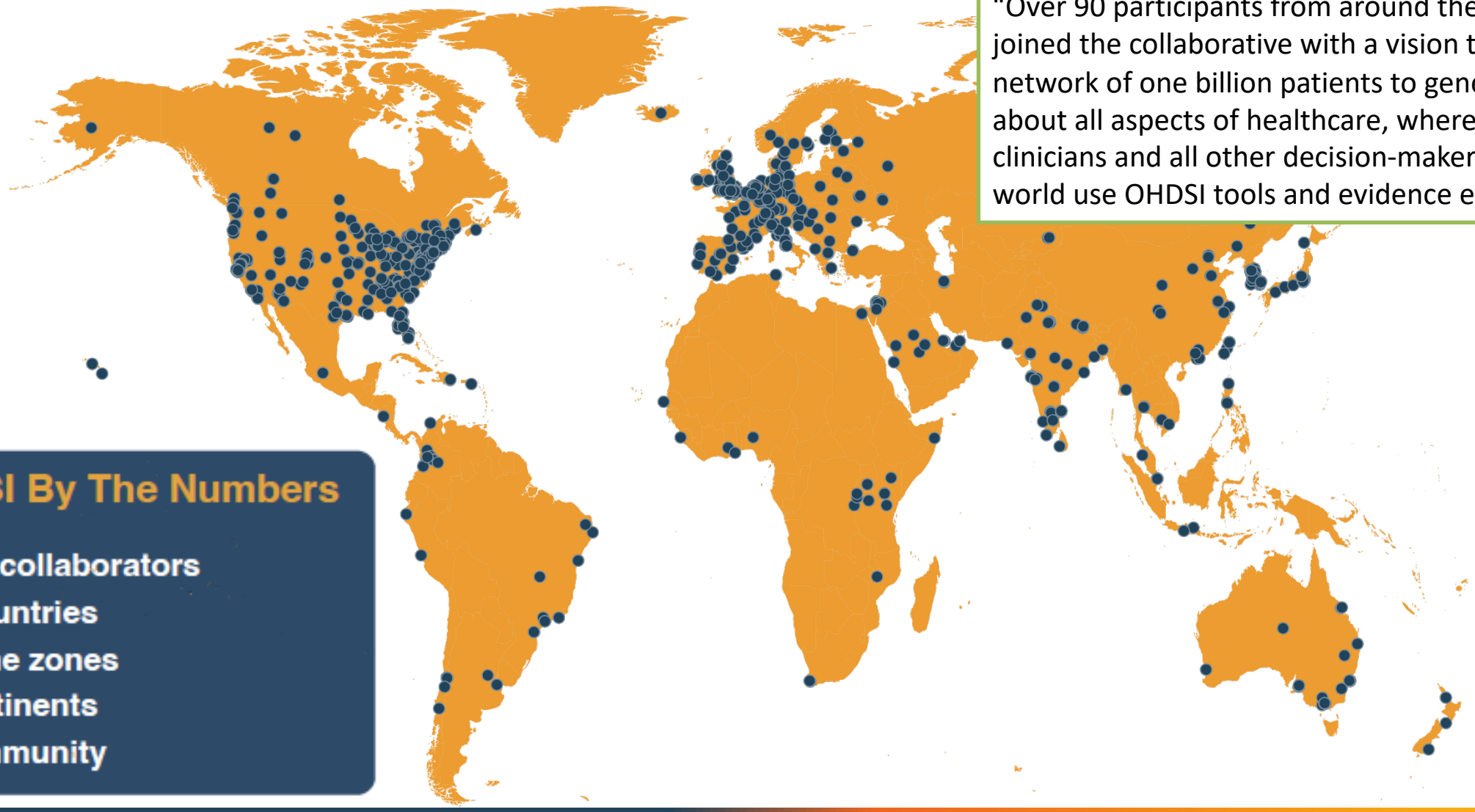
- 58 databases using OMOP CDM
- >200 million unique patient records
- “it is feasible to impose a strong information model …represent a significant fraction of the world’s population”

OMOP CDM Users By The Numbers

- **534 data sources**
- **49 countries**
- **956 million unique patient records (12% of world’s population)**

Map of collaborators (2023)

Hripcsak et al, MedInfo 2015:
"Over 90 participants from around the world have joined the collaborative with a vision to access a network of one billion patients to generate evidence about all aspects of healthcare, where patients, clinicians and all other decision-makers around the world use OHDSI tools and evidence every day."



OHDSI By The Numbers

- 3,758 collaborators
- 83 countries
- 21 time zones
- 6 continents
- 1 community

Join by Web **PollEv.com/patrickryan800**

What was your favorite OHDSI highlight over the last 10 years?

Nobody has responded yet.

Hang tight! Responses are coming in.

Join by Web **PollEv.com/patrickryan800**

If you could give OHDSI a birthday present, what would it be?

Nobody has responded yet.

Hang tight! Responses are coming in.