



Building Data Capacity for Patient-Centered Outcomes Research: Perspectives from the OHDSI community

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OHDSI to advance the science of observational research



OHDSI
OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

- OHDSI is an open science community, founded by scientists at J&J, Columbia University, Stanford, UCLA, Regenstrief Institute, and Iqvia
- OHDSI is an **open multi-stakeholder**, interdisciplinary collaborative with a mission to improve health by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care
- OHDSI is driving development and adoption of **open community data standards, open source analysis software, and open science best practices** within regulators, academia, industry, payors, and health systems

GLOBAL OHDSI NETWORK - *Industry, Academia, Government*



>2,100

*Researchers in
epidemiology,
statistics, informatics,
health policy, and
clinical sciences*

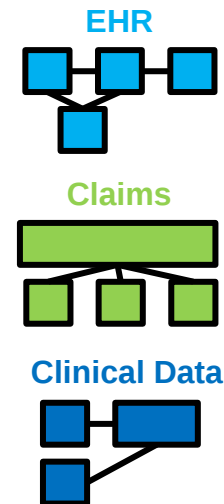
>150

*Databases
Included*

>2B

*Patient records
Represented*

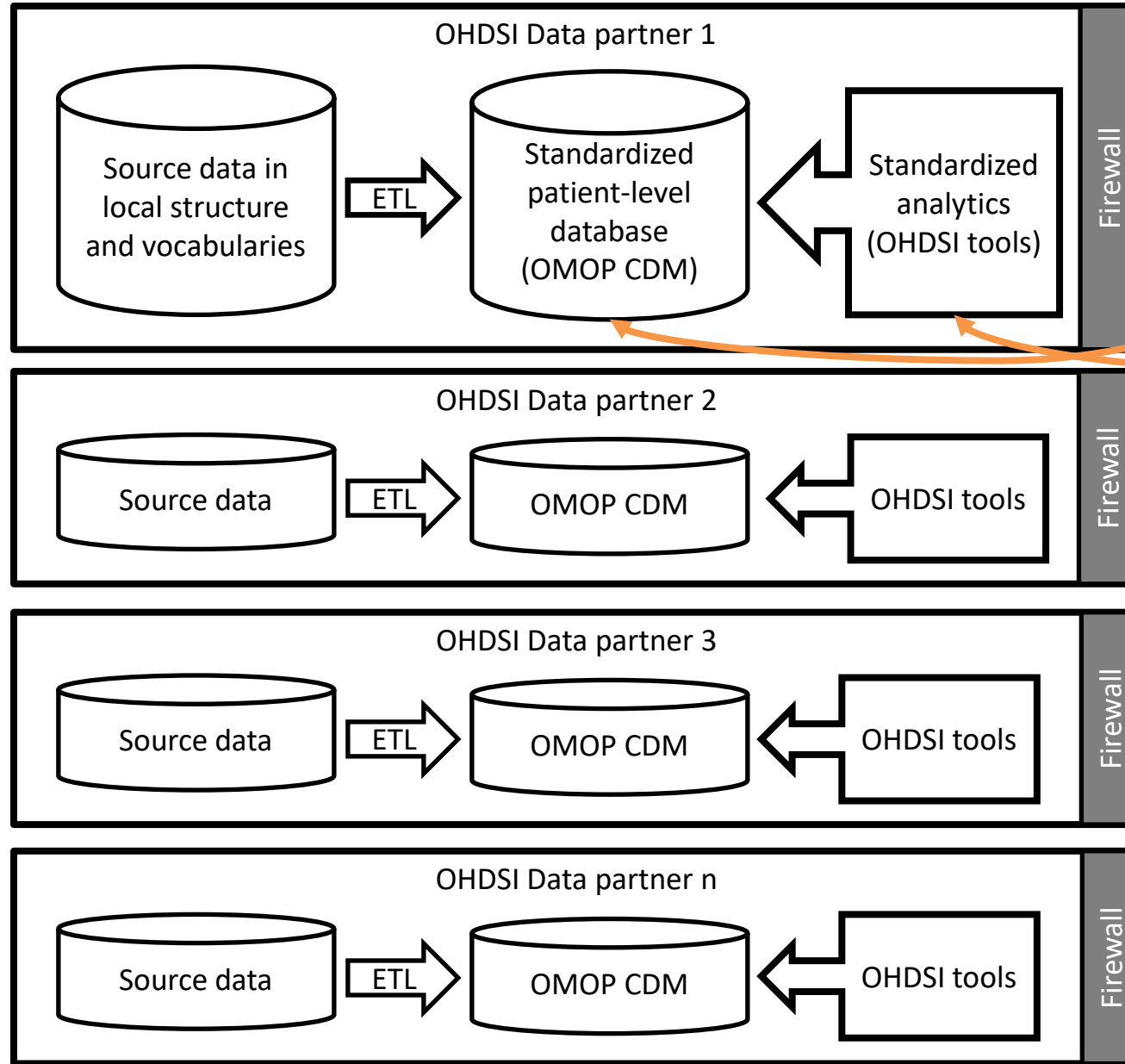
OMOP DRIVING RWE



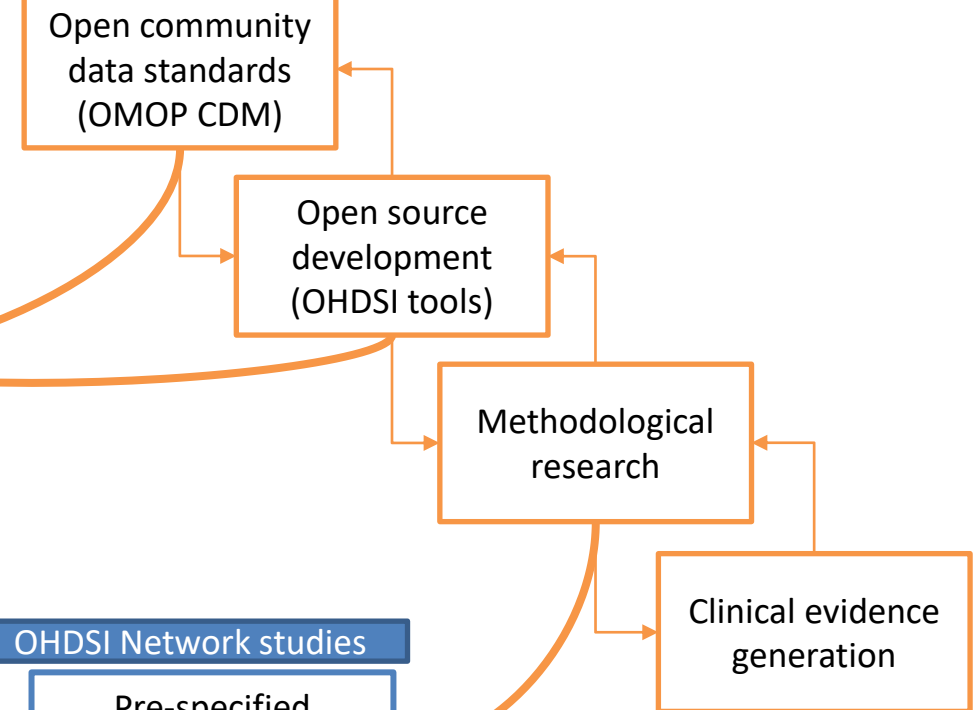
- A** Clinical Characterization
- B** Population-level effect estimation
- C** Patient-level prediction

OHDSI Community

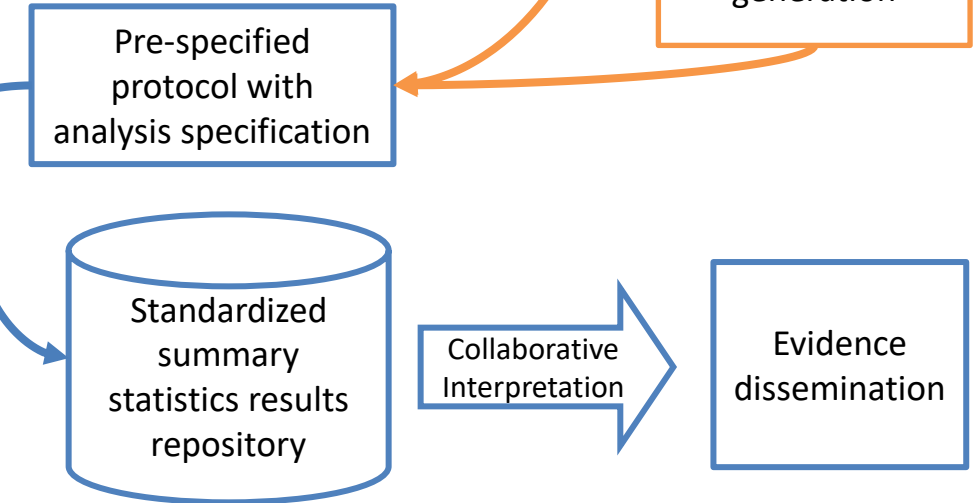
OHDSI data network



OHDSI collaborations



OHDSI Network studies





Data standards are a means to an end, not an end in itself

- What *data standards* could make the PCOR data infrastructure more useful for research and other data needs?
- What *data standards* are likely to become more relevant looking forward?
- What needs to be prioritized?



- What **evidence** would be useful to improve health policy and health care, which could be reliably generated by the PCOR data infrastructure?
- How can *data standards* enable real-world **analytics** to meet the relevant **evidence** needs moving forward?
- What needs to be prioritized?



Desired attributes for reliable evidence

Desired attribute	Question	Researcher	Data	Analysis		Result
Repeatable	Identical	Identical	Identical	Identical	=	Identical
Reproducible	Identical	Different	Identical	Identical	=	Identical
Replicable	Identical	Same or different	Similar	Identical	=	Similar
Generalizable	Identical	Same or different	Different	Identical	=	Similar
Robust	Identical	Same or different	Same or different	Different	=	Similar
Calibrated	Similar (controls)	Identical	Identical	Identical	=	Statistically consistent

- Data standards are necessary to enable replicability, generalizability, and robustness
- Data standards without standardized analytics are not sufficient to ensure reliable evidence
- Standards limited to US data are harmful for US population; public health questions require global data to generate global evidence



Delineating the roles of standards to enable evidence

How can *data standards* enable real-world **analytics** to meet the relevant **evidence** needs moving forward?

What **evidence** would be useful to improve health policy and health care?

Data standards to enable data exchange



Data standards to harmonize data structure and enable analytics



Analytics standards to generate and disseminate evidence



Vocabulary standards to harmonize data content and enable analytics



Characterization:

Who are the patients exposed to medical interventions?
How often do outcomes occur amongst those patients?

Estimation:

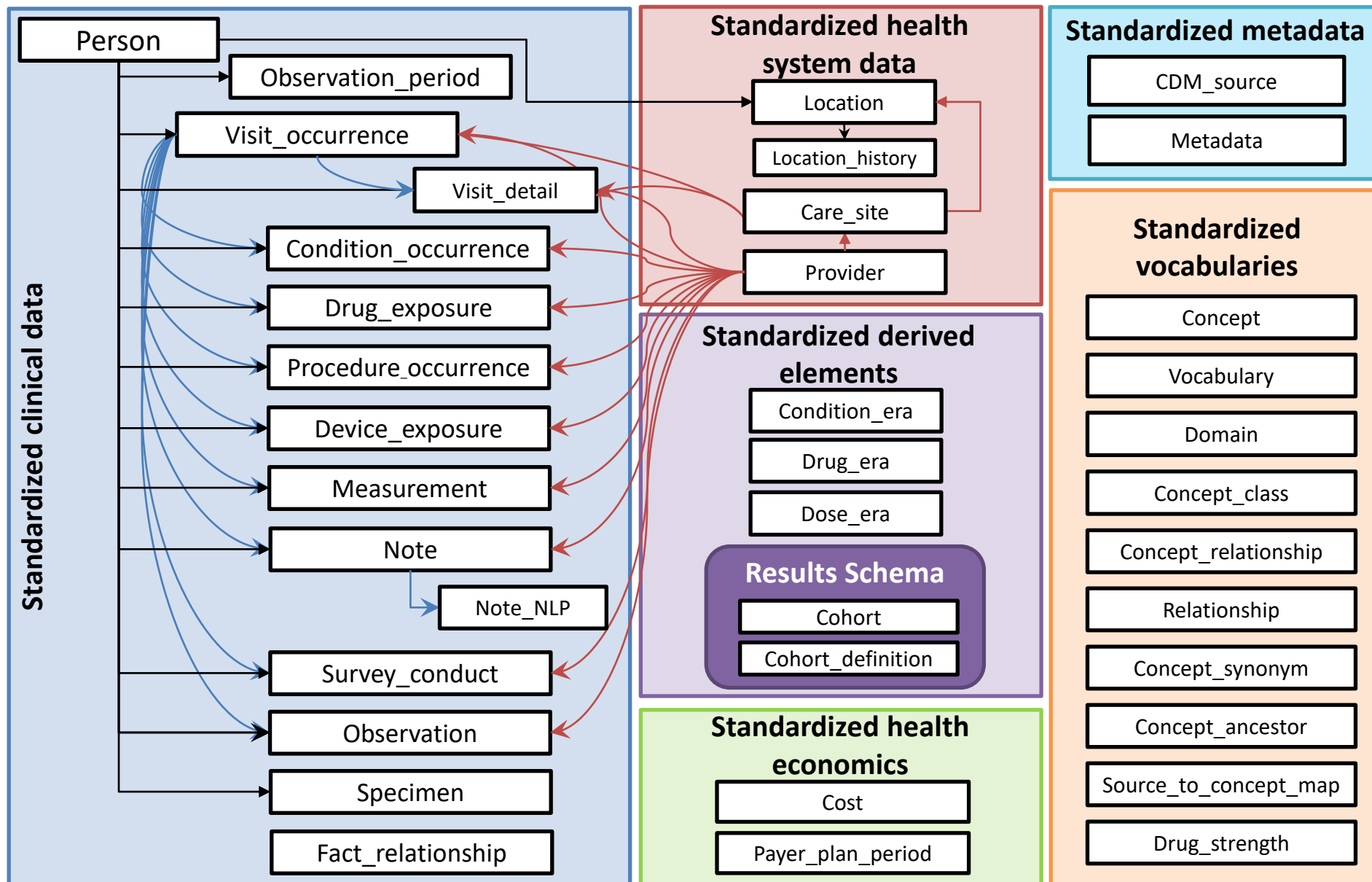
Is the risk of outcome causally related to exposure?
How does the risk compare with alternative interventions?

Prediction:

Which risks can be actionably predicted with available data?
Which patients are at highest risk of adverse events?



Open community data standard to enable analytics: OMOP Common Data Model



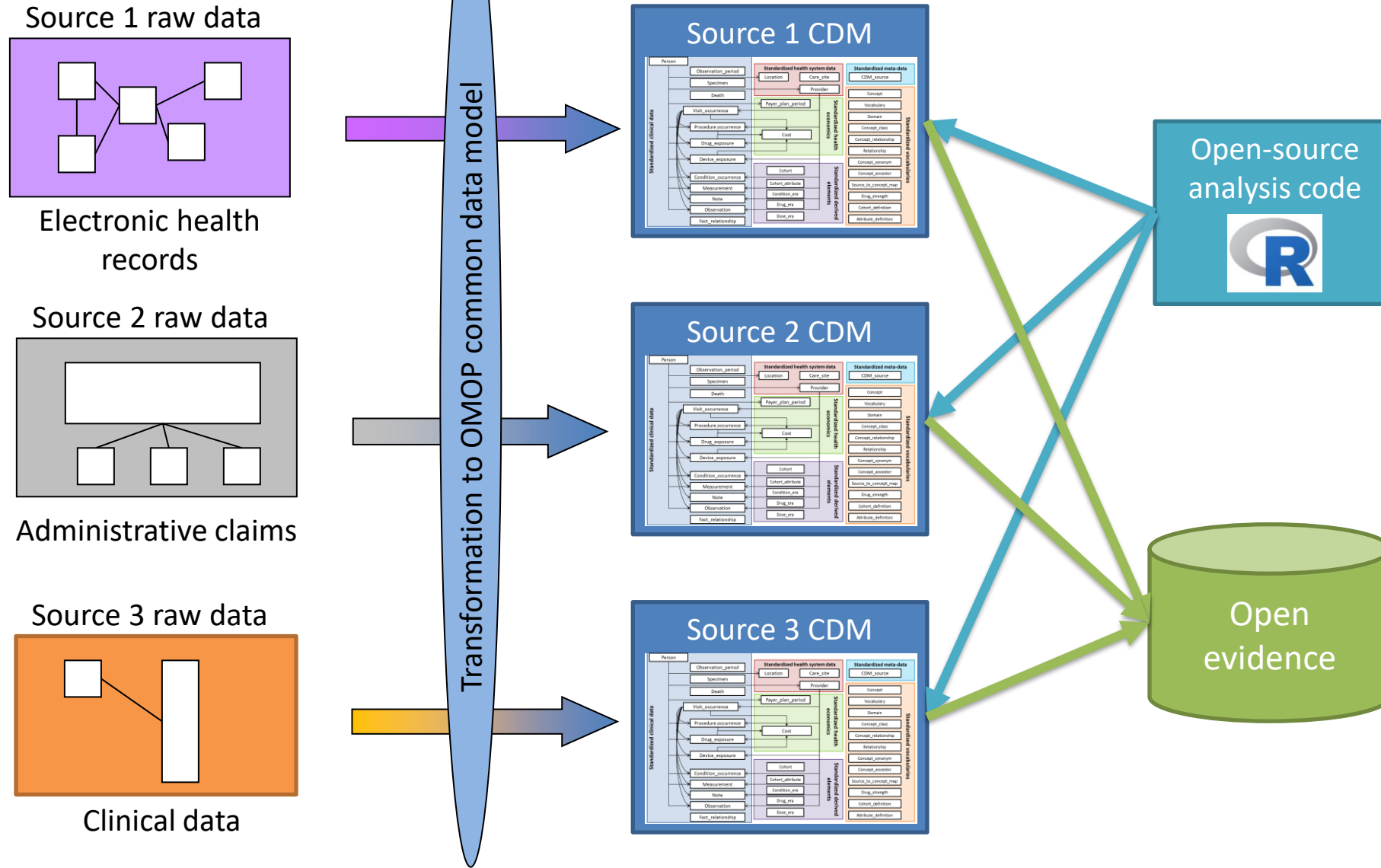


OHDSI's standardized vocabularies to harmonize data content and enable analytics

- 164 Vocabularies across 41 domains
 - MU3 standards: SNOMED, RxNorm, LOINC
 - Disparate sources: ICD9CM, ICD10(CM), Read, NDC, Gemsript, CPT4, HCPCS...
- >9.5 million concepts
 - >3.4 million standard concepts
 - >5.4 million source codes
 - >674,000 classification concepts
- >57 million concept relationships
- >86 million ancestral relationships



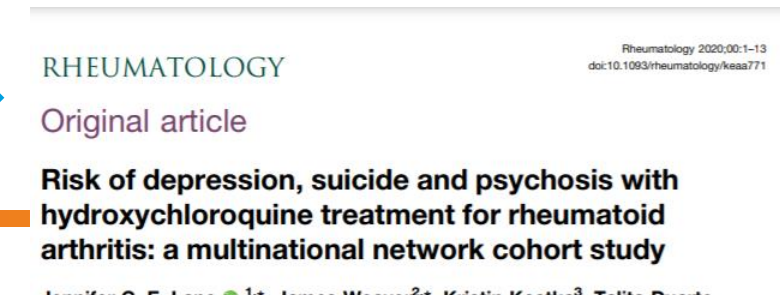
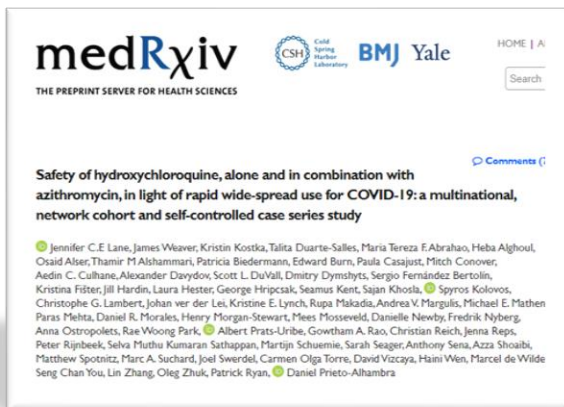
Common data model and standardized vocabularies to enable standardized analytics





Standards enabling evidence for regulators: Safety of hydroxychloroquine (HCQ)

- Evidence needed around the safety of HCQ alone and in combination with azithromycin (AZ)
- Standardized analytics: comparative cohort design with large-scale propensity adjustment
- Standardized data: 14 databases (claims and EHR) from 6 countries, all using OMOP CDM
- Findings: In RA population, HCQ alone is generally safe but in combination with AZ it shows a doubling of risk of 30-day cardiovascular mortality.





Standards enabling evidence for policy: COVID-19 treatment utilization patterns

thebmj

RESEARCH

OPEN ACCESS

Check for updates

Use of repurposed and adjuvant drugs in hospital patients with covid-19: multinational network cohort study

Albert Prats-Urbe,¹ Anthony G Sena,^{2,3} Lana Yin Hui Lai, Heba Alghoul,⁷ Osaid Alser,⁸ Thamir M Alshammari,⁹ Cai Paula Casajust,¹² Dalia Dawoud,^{13,14} Asieh Golozar,^{15,16} Paras P Mehta,¹⁸ Mengchun Gong,¹⁹ Daniel R Morales,²⁰ Martina Recalde,^{24,25} Elena Roel,^{24,25} Karishma Shah,⁵ N Vignesh Subbian,²⁶ David Vizcaya,²⁷ Lin Zhang,^{28,29} Ying Jaehyeong Cho,³¹ Kristine E Lynch,³² Michael E Matheny, Peter R Rijnbeek,³ George Hripcsak,³⁶ Jennifer CE Lane,⁵ Marc A Suchard,³⁸ Talita Duarte-Salles,²⁴ Kristin Kostka,³ Daniel Prieto-Alhambra¹

ABSTRACT OBJECTIVE

To investigate the use of repurposed and adjuvant drugs in patients admitted to hospital with covid-19 across three continents.

DESIGN

Multinational network cohort study.

SETTING

Hospital electronic health records from the United States, Spain, and China, and nationwide claims data from South Korea.

PARTICIPANTS

303 264 patients admitted to hospital with covid-19 from January 2020 to December 2020.

MAIN OUTCOME MEASURES

Prescriptions or dispensations of any drug on or 30

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(34.9%)
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and 238
varied g
being ei
vitamin
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the rest
corticost
CONCLL
Multiple
the covi
and ten

February 2020

4 February Wang et al - Remdesivir and chloroquine effectively inhibit covid-19 in vitro

March 2020

9 March Yao et al - Hydroxychloroquine shows superior in vitro activity to chloroquine
19 March President Trump promotes hydroxychloroquine in press conference
20 March Gautret et al - Open-label non-randomized clinical trial shows effectiveness
28 March US Food and Drug Administration issues an emergency use authorisation
31 March Chen et al - Preprint of a randomised controlled trial suggests that hydroxychloroquine reduces time to clinical recovery

April 2020

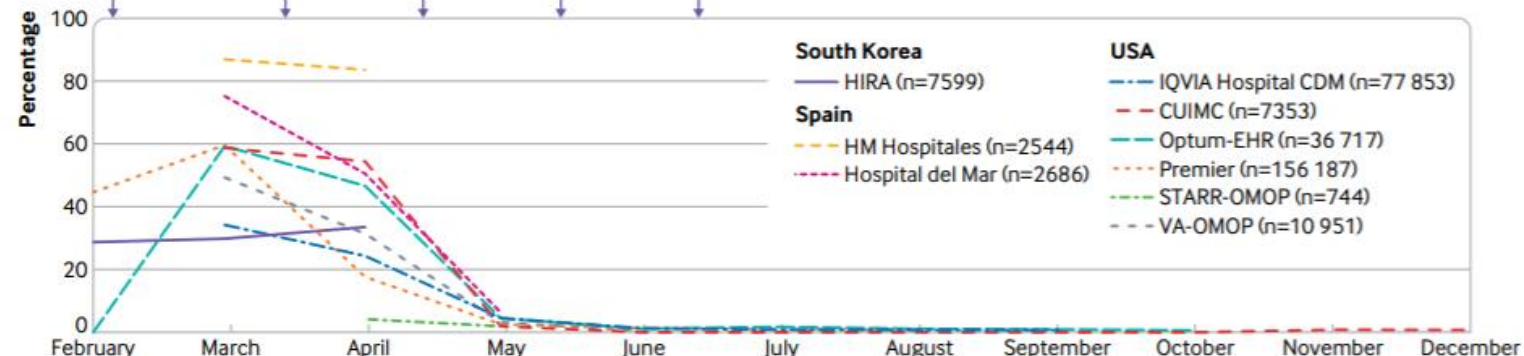
10 April Lane et al - Observational data show that azithromycin combined with hydroxychloroquine may increase cardiovascular mortality
24 April FDA and European Medicines Agency caution against the use of hydroxychloroquine owing to potential heart rhythm problems

May 2020

7 May Geleris et al - Lack of effectiveness of hydroxychloroquine on observational data
28 May WHO halts hydroxychloroquine arm of Solidarity trial

June 2020

8 June Recovery trial press note shows that hydroxychloroquine has no effect on covid-19
15 June FDA revokes emergency use ruling for hydroxychloroquine



For numbered affiliations see end of the article.

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Additional material is published online only. To view please visit the journal online.

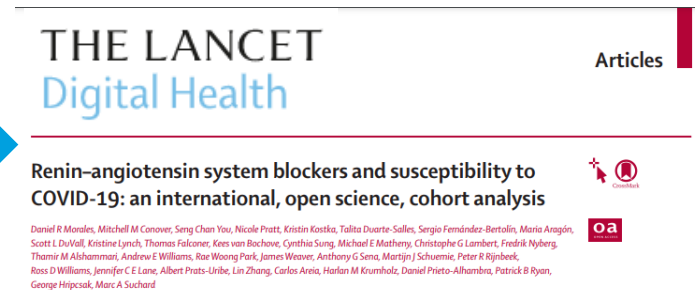
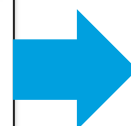
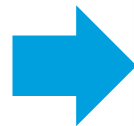
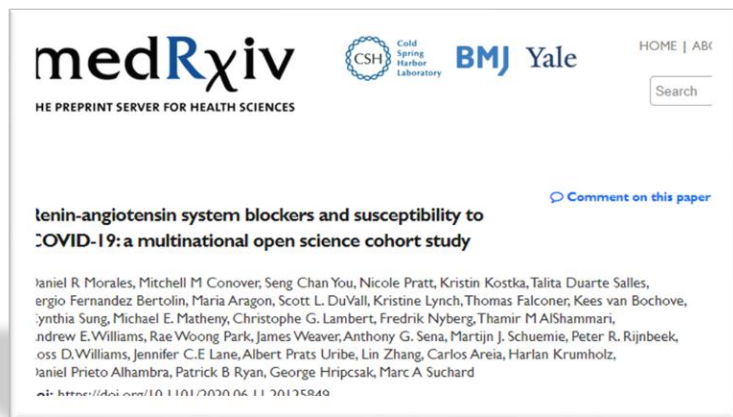
Cite this as: *BMJ* 2021;373:n1038
<http://dx.doi.org/10.1136/bmj.n1038>

Accepted: 16 April 2021



Data standards are part of methodological standards for reliable evidence

- 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.



Take-home messages

- Data standards should be driven by evidence needs
- Complementary standards required across the evidence generation lifecycle
 - Data standards for exchange
 - Data standards for structure for analytics
 - Vocabulary standards for data content and analytics
 - Analytic standards for evidence generation and dissemination
- Reliable evidence is strengthened by disparate data and analytics standardized within a common shared framework
 - Data network should focus on depth and breadth as required for evidence needs
 - Open science enables adoption of data standards and analytic best practices
 - International collaboration is possible with international standards