

IQVIA Federated Data Modernization



Data Modernization using OMOP CDM



Overview

Join us for a discussion around the data standardization and harmonization utilizing the (Observational Medical Outcome Partnership (OMOP) common data model (CDM) and how it is used to generate reproducible, accurate, and well-calibrated evidence-based analytics at scale.

Key areas to be discussed include:

- Real-world data standardization and harmonization efforts
- The impact of RWD during the COVID-19 pandemic
- How OMOP can support regulatory decision making
- Data standardization and harmonization through OHDSI OMOP
- Federated network government adoptions
- Public health policy evidence generation at scale



Presenters



Mui Van Zandt

VP/GM, Real-World Data and Technology



Atif Adam, Ph.D., MD, MPH
Associate Director in Epidemiology





Regulatory adoption of data standardization

Mui Van Zandt



Regulators are increasingly interested in how RWE may support regulatory decision-making



Despite <u>challenges</u>, traditional RCTs are the gold standard for drug evidence development

- Increasingly time and resource intensive to conduct
- Not broadly representative of the patients seen in actual clinical care
- May be unethical or infeasible to perform given small patient population sizes



RWD/RWE can be used to demonstrate medical product safety and effectiveness

- RWE reflects broader patient populations
- RCTs may not be generating evidence on endpoints that are truly useful to patients, providers, or payers
- RWE can fill remaining downstream evidence gaps



RWD/RWE can be used to improve the <u>efficiency</u> of clinical research

 Growing base of RWD from electronic health information infrastructure has enabled routine and increasingly robust collection of digital data at the point of patient care



There is an impressive and growing array of real-world data sources

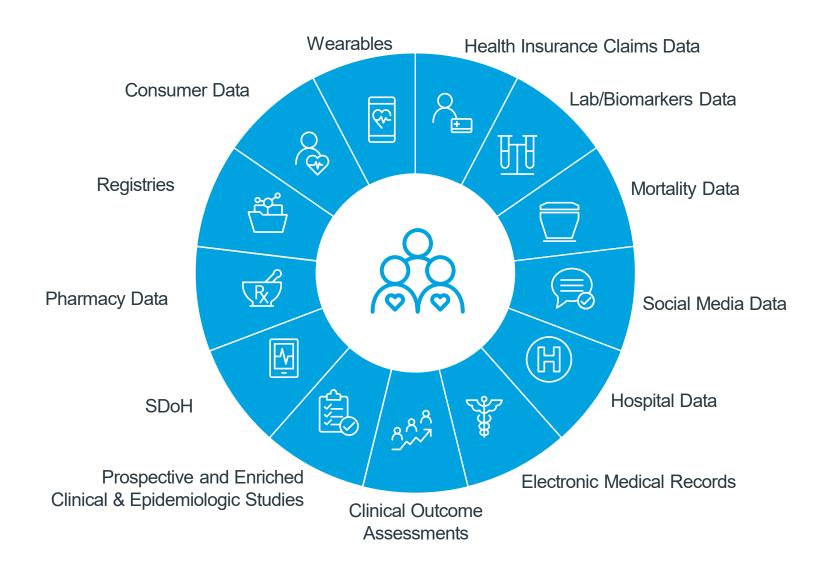


Real World Data (RWD)

Data relating to patient health status and/or the delivery of health care collected from a variety of sources

Real World Evidence (RWE)

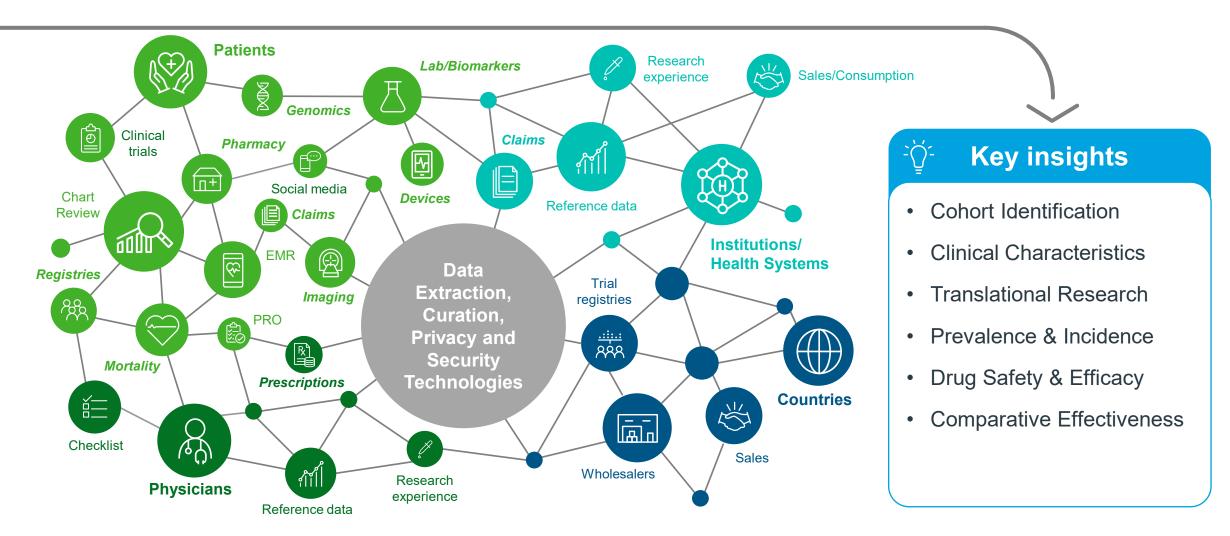
Clinical evidence about the usage and potential benefits/risks of a medical product derived from the analysis of RWD





Increased demand for data standardization

Real-world is too imperfect and has too many challenges



Data standardization and harmonization through OHDSI



Why Choose OHDSI/OMOP

- Fast, reliable studies across a series of datasets and data types
- Reduced cost of ownership including understanding coding schemes, writing statistical programs across databases or developing software
- Expanded data access via the OHDSI network and remote multi-center database studies



OHDSI Collaborators

- 2,900 users
- 29 workgroups
- 46,900 posts on 5,700 topics

OHDSI Network

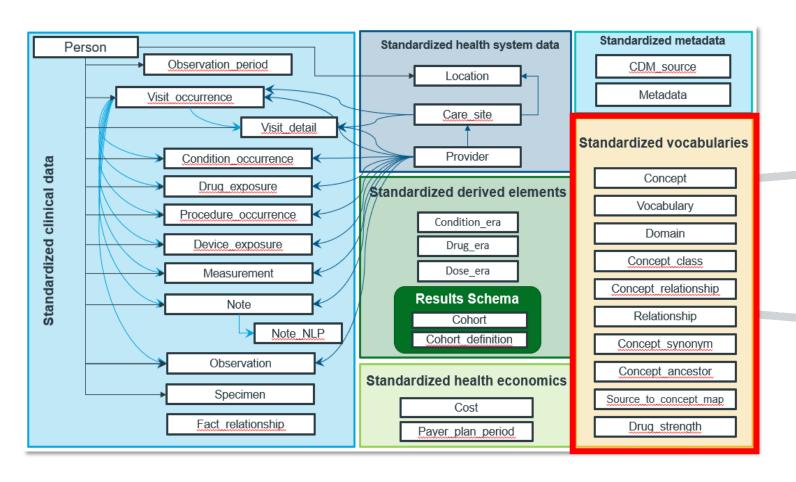
- >320+ databases
- 34 countries
- 2.7B patient records, 369M ex-US

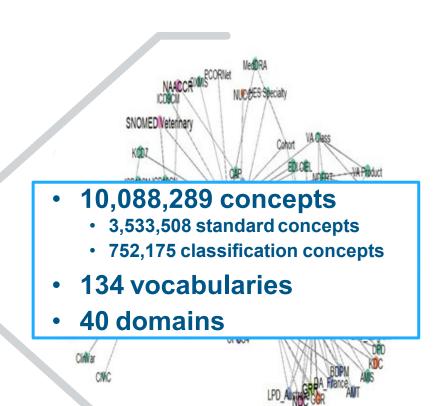
https://ohdsi.org/



OMOP common data model (CDM)

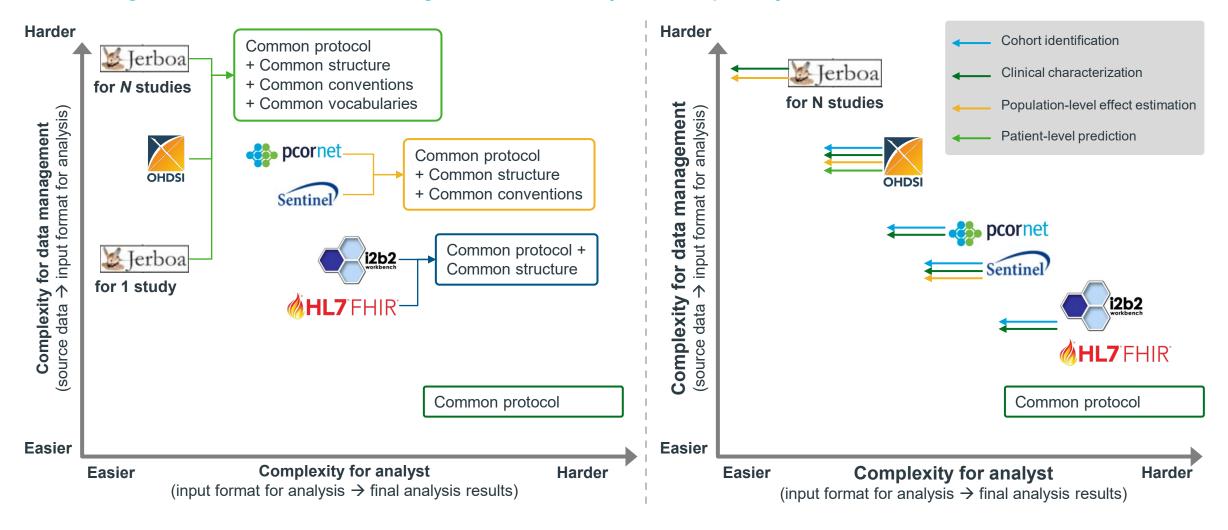
Ontologies are critical when designing at data models





Comparison of common data models

Balancing trade-offs in data management vs. analysis complexity



Global Government Adoption of OHDSI







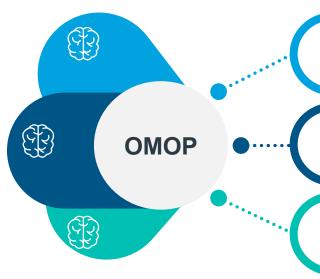






Collaboration across standards

OHDSI/FHIR



OMOP CDM

- Dual source platform that supports both data science and application deployment
- Use of study results as actionable data to drive treatment decisions

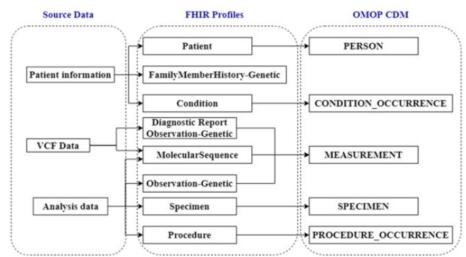
Improved Data Quality

Leveraging the OMOP standard data models and data elements defined in FHIR ensures consistent and accurate data capture, which improves the validity and reliability of observational studies.

Real-time Analysis

Real-time analysis of FHIR-compliant data, which can be useful for real-world evidence generation and other applications.

Home > HL7 International and OHDSI Announce Collaboration to Provide Single Common Data Model for Sharing Information in Clinical Care and Observational Research **HL7 International and OHDSI Announce Collaboration to Provide Single Common Data** Model for Sharing Information in Clinical Care and **Observational Research** Health Level Seven International (HL7®) and the Observational Health Data Sciences and Informatics (OHDSI) network today announced a collaboration to address the sharing and tracking of data in the healthcare and research industries by creating a single common data model. The organizations will integrate HL7 Fast Healthcare Interoperability Resources (FHIR®) and OHDSI's Observational Medical Outcomes Partnership (OMOP) common data model to achieve this goal. HL7 International CEO Dr. Charles Jaffe, M.D., Ph.D., underscored the significance of this partnership. "The Covid-19 pandemic has emphasized the need to share global health and research data." He continued. "Collaboration with OHDSI is critical to solving this challenge and will help our mutual vision of a world in which everyone can securely access and use the right



https://www.researchgate.net/figure/Data-Mapping-Concept-for-FHIR-to-OMOP-using-MEASUREMENT fig4 354739998



IQVIA OMOP CDM Services and Support

Building your own OMOP capabilities, leveraging IQVIA consulting and technical services



Network

Global federated network

- Federated network coordinating center
- Data partnership in US, EU, and Asia



Data Analytics

Use of reproducible, well-calibrated analysis

- Protocol driven multi-database analysis
- Deliver reliable, cost-, time-, and resource effective evidence at scale



Globally scalable studies using the federated network model with data partners of varying data types from around the world.

The federated research network helps to reduce administrative barriers by eliminating the need to access patient-level data.

Analyses are reproducible, saving on time and resources to generate reliable evidence at scale.



Software, ETL, and SME

High quality mapping from source to OMOP

- Software to assist with conversion
- Team of expertise to ensure accurate mapping
- OMOP conversion expertise
- SME consultancy on OMOP conversions



Training

Highly experience trainers

- OMOP CDM/Vocabulary
- Conversion workshop
- Standard analytics training
- Leveraging standardizations to perform multi-center research

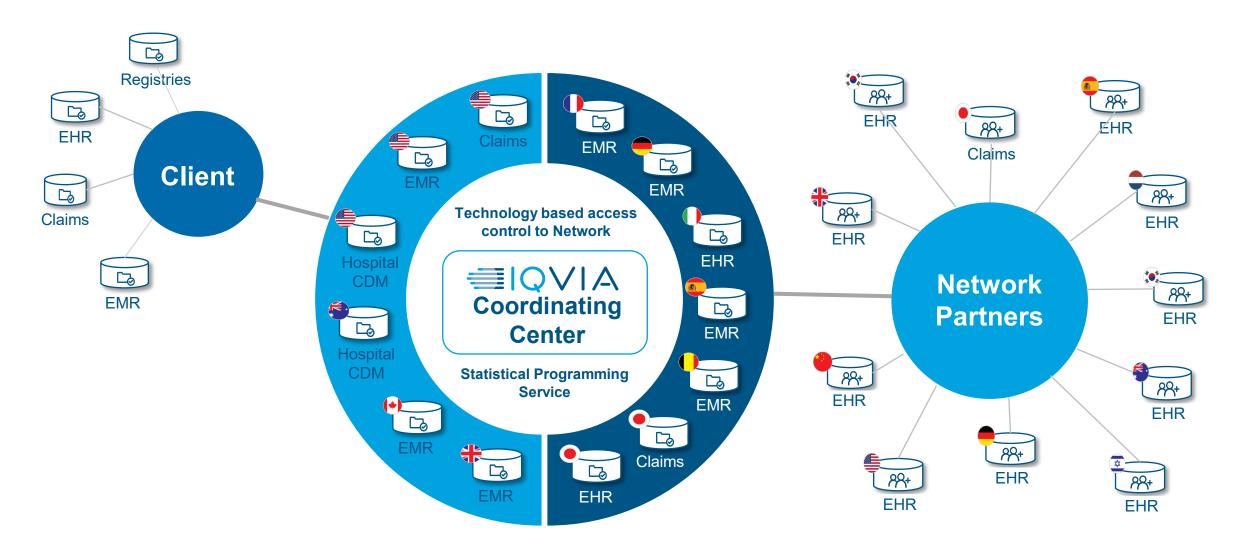


Leverage industry expert to create a high quality standardized OMOP data asset

Top notch training accepted/referred by the OHDSI community



IQVIA OMOP Research Network



FDA Best Federated Data Network Overview

Study Investigations & Adverse Events

- Studies:
 - · Simple Rapid queries
 - Cohort characterization
 - Safety & Surveillance
 - Pharmacoepidemiology
- Adverse Event Reporting



Data Partners

- Run studies
- Various data types (claims, EHR)





























- Study protocol development
- Develop analytical packages
- External validation
- Coordinate data partner activities
- Program management



Data Quality

- Standardized data quality pipeline
- Establish data quality application for data quality assessment



Scientific Advisory

- Develop reproducible analytics tools and scientific methods
- Maintain data standardization and data quality standards
- Adoption of OMOP CDM globally



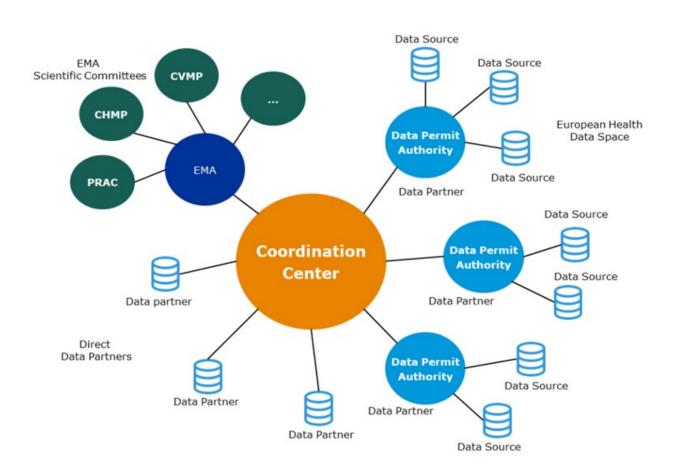


■IQVIA



The DARWIN EU® Initiative Overview

A game changer in the structural use of health data for regulatory purposes in the EU



Unprecedented productivity/throughput

DARWIN EU will establish a **scalable** data analysis IT platform and distributed **OMOP** data network of **40 data partners** that will output **145 studies/year**.

>> This has never been done before!

Federated network model

DARWIN EU will utilize a federated network model to run large-scale analyses across the data partner databases.

The **advantage** of a federated network model is analyses are run within the data partner's institution:

- Only the results are returned
- There is no need to access patient-level data





Evidence-based analysis utilizing OMOP CDM and IQVIA Federated Network

Atif Adam

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FDA BEST: COVID-19 Vaccine Safety Studies

Key outcomes and communication

Vascular outcomes (RCA)¹

- Four potential AESIs detected
- Adults 65 years and older
- Post-vaccination with Pfizer-BioNTech COVID-19 vaccines
- FDA safety communication Jul 2021

Myocarditis/Pericarditis²

- Potential signal in young, male adults
- Post-vaccination with mRNA COVID-19 vaccines
- Study completion Dec 2021

RCA in adolescents and adults aged 12-64 years³

- 17 outcomes monitored in 3 databases
- Myocarditis/pericarditis signaled in 2 of 3 databases
- Anaphylaxis signaled in all databases
- Study completion Apr 2022

Initial Results of Near Real-Time Safety Monitoring of COVID-19 Vaccines in Persons Aged 65 Years and Older f Share 🔰 Tweet in Linkedin 💟 Email 🖨 Print

July 12, 2 Risk of myocarditis and pericarditis after the COVID-19 mRNA vaccination in the USA: a cohort study in claims FDA has r databases



Hui-Lee Wona*, Mao Hu*, Cindy Ke Zhou, Patricia CLloyd, Kandace L Amend, Daniel C Beachler, Alex Secora, Cheryl N McMahill-Walraven, Yun Lu, Yue Wu, Rachel P Oqilvie, Christian Reich, Djeneba Audrey Djibo, Zhiruo Wan, John D Seeger, Sandia Akhtar, Yixin Jiao, Yoganand Chillarige, Rose Do, John Hornberger, Joyce Obidi, Richard Forshee, Azadeh Shoaibi, Steven A Anderson

19 vaccines

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Background Several passive surveillance systems reported increased risks of myocarditis or pericarditis, or both, after Lancet 2022;399: 2191-99 COVID-19 mRNA vaccination, especially in young men. We used active surveillance from large health-care databases See Comment page 2168 to quantify and enable the direct comparison of the risk of myocarditis or pericarditis, or both, after mRNA-1273 *loint first authors (Moderna) an

Methods We both, identifi evaluated in (O) incideno database. We

Near real-time surveillance of safety outcomes in US COVID-19 vaccine recipients aged 12 to 64 years

Patricia C. Lloyd a, Mao Hu b, Hui-Lee Wong a, Azadeh Shoaibi a, Cindy Ke Zhou a, An-Chi Lo b, Kandace Amend c, Daniel C. Beachler d, Cheryl N. McMahill-Walraven e, Elizabeth R. Smith b, John Seeger c, Alex Secora f, Djeneba Audrey Djibo e, Joyce Obidi a, Yuhui Feng b, Jennifer Song c, Christian Reich f, Charalynn Harris e, Sandia Akhtar b, Robin Clifford C, Nandini Selvam f, Jennifer L. Pigoga e, Yixin Jiao b, Yoganand Chillarige b, Thomas MaCurdy b, Richard Forshee a, Steven A, Anderson a,

- *US Food and Drug Administration, Silver Spring, MD, USA Acumen LLC, Burlingame, CA, USA
- COptum Epidemiology, Boston, MA, USA
- d HealthCore, Inc. Wilmington, DE, USA
- CVS Health Clinical Trial Services, Blue Bell, PA, USA
- IOVIA Falls Church VA USA



^{1.} https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/initial-results-near-real-time-safety-monitoring-covid-19-vaccines-persons-aged-65-vears-and-older

^{2.} Wong, Hui-Lee et al., Risk of myocarditis and pericarditis after the COVID-19 mRNA vaccination in the USA; a cohort study in claims databases. The Lancet, Volume 399, Issue 10342, 2191 – 2199

^{3.} Lloyd PC, Hu M, Wong HL, Shoaibi A, Ke Zhou C, Lo AC, Amend K, Beachler DC, McMahill-Walraven CN, Smith ER, Seeger J, Secora A, Audrey Djibo D, Obidi J, Feng Y, Song J, Reich C, Harris C, Akhtar S, Clifford R, Selvam N, Pigoga JL, Jiao Y, Chillarige Y, MaCurdy T, Forshee R, Anderson SA. Near real-time surveillance of safety outcomes in US COVID-19 vaccine recipients aged 12 to 64 years. Vaccine. 2022 Sep 27:S0264-410X(22)01167-7. doi: 10.1016/j.vaccine.2022.09.060. Epub ahead of print. PMID: 36195472; PMCID: PMC9513329.

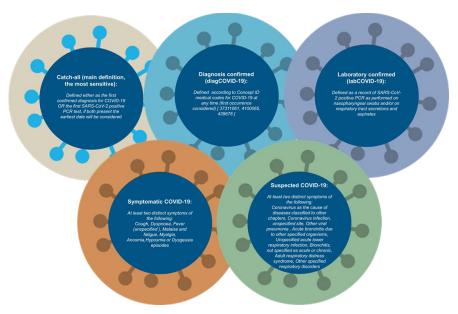
E-CORE (Evidence for COVID-19 Observational Research Europe)

In 2020, the E-CORE network was created in response to an EMA call with the aim to conduct multicentre cohort studies on the use of medicines to treat patients with COVID-19, thus accelerate the generation of robust real-world evidence of therapies for COVID-19.

E-CORE is:

- a federated network with data sources mapped to the OMOP common data model (CDM) to enable common analytics.
- a collaboration between multiple institutions: academics, contract research organizations and data partners with expertise in conducting pharmacoepidemiologic studies and access to health databases.
- Consisting of
 - Administrative Centre
 - Study Coordinating Centre
 - 3. Data Partners
 - 4. Scientific Advisory Board

A proof of concept study was conducted focusing on use of systemic glucocorticoids in the treatment of COVID-19 in the primary and secondary care setting.



EU PAS Registration: EUPAS38759

https://www.encepp.eu/encepp/viewResource.htm?id=38760

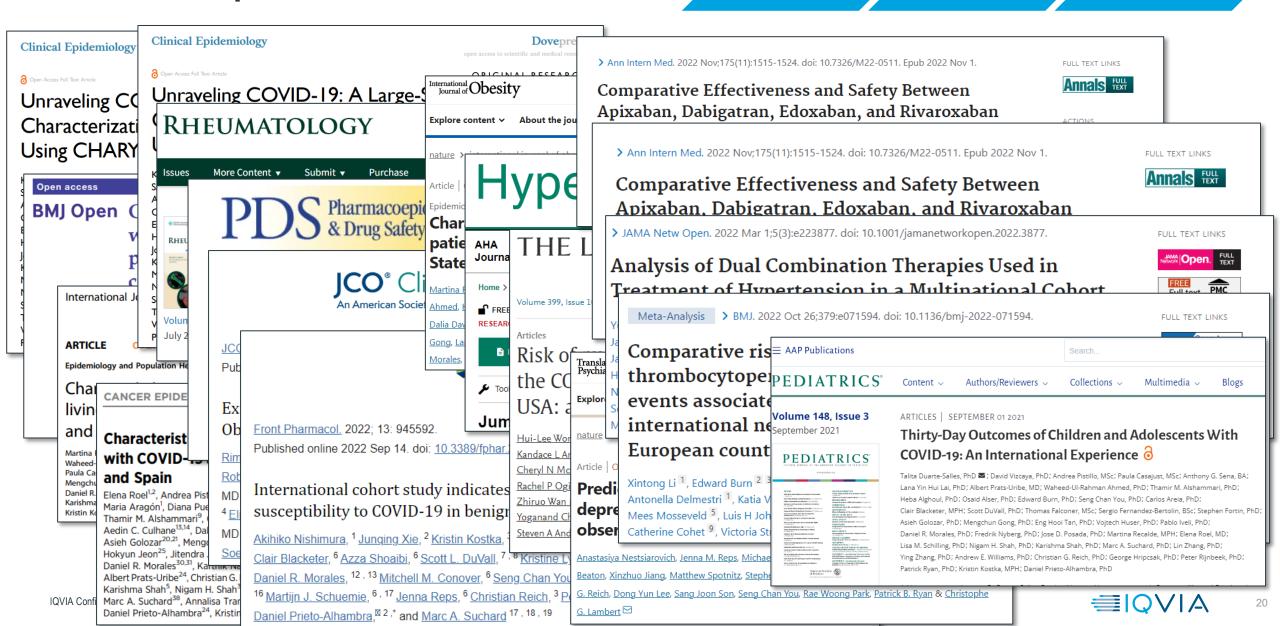
Twelve databases from nine countries (**Germany**: IQVIA DA and a University hospital; **France**: IQVIA LDP; **Belgium**: IQVIA LPD, **Italy**: IQVIA LDP; **UK**: IMRD; **Spain**: SIDIAP, HM Hospitales and Parc Salut Mar Barcelona (IMASIS); **the Netherlands**: IPCI, **Serbia**: Clinerion/Heliant and **US**: Hospital Charge Data Master). Of these, six encompass the primary/ambulatory care setting and six encompass the hospital care setting.



Characterization

Estimation

Prediction



IQVIA OMOP Productized Analytics Publications

Infectious Disease publications



Cardiovascular publications



Oncology publications



Methods publications



Mental Health publications



40 Publications Since 2017

JCO Clinical Cancer **Informatics**

Clincal Pharmacology Therapies

Science Reports

Translational Psychiatry

International Journal of Obesity

Journal Of Biomedical Informatics

Academic

Partners

JAMA The The Lancet

Lancet Rheumatology

Hypertension

Rheumatology **Blood Advances**

Pediatrics

Pharmacoepidemiology and Drug Safety

> Frontiers in **Pharmacology**

> > **PLoS One**

British Medical Journal









OHDSI



- Disease & Treatment Patterns
- Patient-level Clinical Evidence
- Healthcare Costs
- Policy Levers

Research Areas

Drug safety

- Drug Efficacy
- Descriptive statistics
- Risk analysis
- Comparative studies
- Method development and validation
- Combination Therapy
- Vaccines



Key takeaways

Thank you for your attendance



OMOP allows integration of clinical and public health data structures that facilitates secure and trusted health data exchange between public health and private partners



IQVIA has developed standardized tools and methods that support response-ready surveillance systems for automated forecasting and analytics



IQVIA is a leading partner with regulatory agencies on implementation, coordination and execution of RWE network studies, both in the US and globally.



IQVIA OMOP has led and collaborated with diverse health stakeholders on publications, policy strategies and clinical trainings across multiple disease areas

Contact



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Thank you