EUROPEAN OHDSI SYMPOSIUM
June 24th 2022 Rotterdam

“Welcome aboard!”

Organised by:
Erasmus MC
Health Data Science
Welcome to the European OHDSI Journey

Prof. Dr. Ir. Peter R. Rijnbeek
Professor of Medical Informatics
Chair Department of Medical Informatics
Erasmus MC, The Netherlands
Thank you for your support!
Welcome on the SS Rotterdam

The SS Rotterdam – ‘La Grande Dame’
Launched on 14 December 1956 here in Rotterdam
Originally served as a transatlantic line to connect Rotterdam with New York
Objectives of OHDSI Europe

• Enable the generation of reliable evidence from European health data: promote the adoption of the OMOP-CDM and analytics.
• Focus on European Challenges and Opportunities.
• Community building
  – Point of contact for all stakeholders
  – Training of stakeholders
  – Stimulate national and international collaborations in Europe
  – Organization of European OHDSI Symposia
First Annual OHDSI Symposium, March 23th 2018

• 200 participants
• 24 countries
• 40 posters
• 5 software demos
• 2 full day tutorials
Second Annual OHDSI Symposium, March 29th 2019

- 250 participants
- 27 countries
- 35 posters
- 8 software demos
- 5 full day tutorials
European OHDSI Symposium 2020 Cancelled

Prof. Daniel Prieto Alhambra

250 registered participants
Meeting Goals Third OHDSI Symposium

- Provide a platform to stimulate community building
- Enable the community to share their plans and results
- Educate and train the community through a workshop (Saturday) and multiple Workgroup Meetings (Sunday)
Breakdown of Participants: 34 Countries

- Netherlands
- USA
- Belgium
- France
- Italy
- Ukraine
- Israel
- Serbia
- Brazil
- Estonia
- Austria
- Finland
- Ireland
- Australia
- Guatemala
- Luxembourg
- Saudi Arabia
- UK
- Spain
- Germany
- Denmark
- South Korea
- Greece
- Norway
- Switzerland
- Portugal
- Canada
- Hungary
- Lithuania
- Belarus
- Ghana
- Hong Kong
- Malawi
- Turkey
Breakdown of Participants: Stakeholders

Technology
Academia
Health System
Pharmaceutical
Government
Relationship with OHDSI

- New to OHDSI: 85
- Participate OHDSI meetings: 125
- Database conversion: 87
- OMOP CDM instance: 107
- Use OHDSI tools & methods: 136
- Participate OHDSI Forum: 53
- Participate OHDSI studies: 67
- Visited OHDSI Europe Symp: 62
- Visited OHDSI Global Symp: 105

N=350
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<thead>
<tr>
<th>Time</th>
<th>Description</th>
<th>Location</th>
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<tr>
<td>9:10 – 9:40</td>
<td><strong>Journey of OHDSI: Where have we been?</strong> Speaker: George Hripcsak, MD, MS, Vivian Beaumont Allen Professor and Chair, Biomedical Informatics, Columbia University Medical Center</td>
<td>Theatre</td>
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<tr>
<td>9:40 – 11:00</td>
<td><strong>A Cruise around the OHDSI Europe Community</strong> Moderator: Nigel Hughes, Janssen Research and Development</td>
<td>Theatre</td>
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<td>11:00 – 11:30</td>
<td><strong>Coffee Break</strong></td>
<td>Queen’s Lounge</td>
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<td>11:30 – 12:45</td>
<td><strong>Rapid fire presentations of collaborators</strong> Moderator: Katia Verhamme, MD, Associate Professor of Use and Analysis of Observational Data, Department of Medical Informatics, Erasmus MC</td>
<td>Theatre</td>
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<tr>
<td>12:45 – 13:00</td>
<td><strong>Findable, standardized data at scale through the EHDEN Database Catalogue</strong> Speaker: Julia Kurps, The Hyve</td>
<td>Theatre</td>
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<td>Time</td>
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<td>13:00 – 14:00</td>
<td>Lunch</td>
<td>La Fontaine &amp; Odyssee Room</td>
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<td>13:00 – 16:15</td>
<td>OHDSI Collaborator Showcase</td>
<td>La Fontaine &amp; Odyssee Room</td>
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</table>
| 14:30 – 15:30| Early Investigators Mentor Meetings  
Lead: Ross Williams, Department of Medical Informatics, Erasmus MC | Queen’s Lounge                    |
| 16:15 – 16:45| Characterizing Adverse Events in COVID-19 infected patients across the OHDSI network  
Speaker: Erica Voss, MPH, Janssen Research and Development, Erasmus MC | Theatre                           |
| 16:45 – 17:00| Data Analysis and Real World Interrogation Network (DARWIN EU®)  
Speaker: Peter Rijnbeek, PhD, Chair, Department of Medical Informatics, Erasmus MC | Theatre                           |
| 17:00 – 17:45| Reaction panel with key stakeholders.  
Moderator: Dani Prieto-Alhambra, MD, PhD Professor of Pharmaco- and Device Epidemiology University of Oxford, Professor of Real World Evidence and Methods Research, Erasmus MC | Theatre                           |
| 17:45 – 18:00| Closure                                                                     | Theatre                           |
| 18:00 – 19:30| Networking Reception                                                        | Queen’s Lounge                    |
Journey of OHDSI: Where have we been?

George Hripcsak, MD, MS

Vivian Beaumont Allen Professor and Chair, Biomedical Informatics, Columbia University Irving Medical Center
A lot has happened in the world since we were last together in Europe...
OHDSI progress at the last in-person European OHDSI Symposium Mar2019

- Community publishing useful work, primarily methodological research (reached 20 papers in 2018)
- Those papers are now widely cited (>6,000 times as of Jun2022)

- Community education resources started to grow, with >25 hours of video content per year, which has now been cumulatively watched for >75,000 hours as of Jun2022

- Community was growing nicely, >500 different authors with work related to OHDSI research by end of 2018
What hasn’t changed since that last time we were all in-person in European OHDSI Symposium?
OHDSI’s mission

To improve health by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care.
OHDSI Community

OHDSI Data partner 1

Source data in local structure and vocabularies

Standardized patient-level database (OMOP CDM)

Standardized analytics (OHDSI tools)

OHDSI Data partner 2

Source data

OMOP CDM

OHDSI tools

OHDSI Data partner 3

Source data

OMOP CDM

OHDSI tools

OHDSI Data partner n

Source data

OMOP CDM

OHDSI tools

OHDSI collaborations

Open community data standards (OMOP CDM)

Open source development (OHDSI tools)

Methodological research

Clinical evidence generation

OHDSI Network studies

Pre-specified protocol with analysis specification

Standardized summary statistics results repository

Collaborative Interpretation

Evidence dissemination

OHDSI data network

Hripcsak Yearb Med Inform 2021
Common data model can enable standardized analytics across a distributed data network.

- **Source 1 raw data**: Electronic health records
- **Source 2 raw data**: Administrative claims
- **Source 3 raw data**: Clinical data

Transformation to common data model:

- **Source 1 CDM**: Need confidence in the quality of the data and its transformation
- **Source 2 CDM**: Need confidence in the quality of the analytics tools and their output
- **Source 3 CDM**: Need confidence in the quality of the analytics tools and their output

Open-source analysis code: R

Open evidence
Complementary evidence to inform the patient journey

Clinical characterization: What happened to them?

Patient-level prediction: What will happen to me?

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

Observation

Inference

Causal inference
What has happened since last time we were all in-person in European OHDSI Symposium?
OHDSI community has grown

- 3,194 collaborators
- 74 countries
- 21 time zones
- 6 continents
- 1 community
OMOP Common Data Model v5.4 has been widely adopted

**Standardized clinical data**
- Person
  - Observation_period
  - Death
  - Visit_occurrence
  - Visit_detail
  - Condition_occurrence
  - Drug_exposure
  - Procedure_occurrence
  - Device_exposure
  - Measurement
  - Observation
  - Note
  - Note_NLP
  - Episode
  - Specimen
  - Fact_relationship

**Standardized health system**
- Location
- Care_site
- Provider

**Standardized vocabularies**
- Concept
- Vocabulary
- Domain
- Concept_class
- Concept_synonym
- Concept_relationship
- Relationship
- Concept_ancestor
- Source_to_concept_map
- Drug_strength

**Standardized derived elements**
- Condition_era
- Drug_era
- Dose_era

**Results schema**
- Cohort
- Cohort_definition

**Standardized health economics**
- Cost
- Payer_plan_period

**Standardized metadata**
- CDM_source
- Metadata

**OHDSI Data Network**
- 331 data sources
  - 284 EHRs
  - 28 administrative claims
- 34 countries
- 810 million unique patient records
OHDSI Standardized vocabularies have expanded

- 10,088,289 concepts
  - 3,533,508 standard concepts
  - 752,175 classification concepts
- 134 vocabularies
- 40 domains
- 76,192,476 concept relationships
- 84,898,314 ancestral relationships
- 3,016,130 concept synonyms
### Open-source software development: HADES

<table>
<thead>
<tr>
<th>Module</th>
<th>Description</th>
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<tr>
<td><strong>CohortMethod</strong></td>
<td>New-user cohort studies using large-scale regression for propensity and outcome models.</td>
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<tr>
<td><strong>SelfControlledCaseSeries</strong></td>
<td>Self-Controlled Case Series analysis using few or many predictors, includes splines for age and seasonality.</td>
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<td><strong>Cyclops</strong></td>
<td>Highly efficient implementation regularized logistic, Poisson and regression.</td>
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<tr>
<td><strong>EvidenceSynthesis</strong></td>
<td>Routines for combining causal effect estimates and study diagnostics across multiple data sites in a distributed study.</td>
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<tr>
<td><strong>ParallelLogger</strong></td>
<td>Support for parallel computation with logging to console, disk, or email.</td>
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<tr>
<td><strong>PatientLevelPrediction</strong></td>
<td>Build and evaluate predictive models for user-specified outcomes, using a wide array of machine learning algorithms.</td>
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<tr>
<td><strong>EmpiricalCalibration</strong></td>
<td>Use negative control exposure-outcome pairs to profile and calibrate a particular analysis design.</td>
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<tr>
<td><strong>BigKnn</strong></td>
<td>A large scale k-nearest neighbor classifier using the Lucene search engine.</td>
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<tr>
<td><strong>MethodEvaluation</strong></td>
<td>Use real data and established reference sets as well as simulations injected in real data to evaluate the performance of methods.</td>
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<tr>
<td><strong>CohortDiagnostics</strong></td>
<td>Generate a wide set of diagnostics to evaluate cohort definitions against databases in the CDM.</td>
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<tr>
<td><strong>Hydra</strong></td>
<td>Hydrating package skeletons into executable R study packages based on specifications in JSON format.</td>
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<tr>
<td><strong>Eunomia</strong></td>
<td>A standard CDM dataset for testing and demonstration purposes that runs on an embedded SQLite database.</td>
</tr>
<tr>
<td><strong>CirceR</strong></td>
<td>An R wrapper for Circe, a library for creating cohort definitions, expressing them as JSON, SQL, or Markdown.</td>
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</table>

**OHDSI HADES packages downloads on CRAN:**

373k times as of Jun 2022

![Cumulative Downloads Chart](chart.png)
Principles of Large-scale Evidence Generation and Evaluation across a Network of Databases (LEGEND)

Martijn J. Schuemie 1,2, Patrick B. Ryan 3,4, Nicole Pratt 5, RuiJun Chen 6,4, Seng Chan You 6, Harlan M. Krumholz 7, David Madigan 8, George Hripcsak 3,9, and Marc A. Suchard 2,10

Large-scale evidence generation and evaluation across a network of databases (LEGEND): assessing validity using hypertension as a case study

Martijn J Schuemie 1,2, Patrick B Ryan 1,3, Nicole Pratt 4, RuiJun Chen 6,4, Seng Chan You 6, Harlan M Krumholz 7, David Madigan 8, George Hripcsak 3,9, and Marc A Suchard 2,10
LEGEND principles

1. LEGEND will generate evidence at a large scale.
2. Dissemination of the evidence will not depend on the estimated effects.
3. LEGEND will generate evidence using a prespecified analysis design.
4. LEGEND will generate evidence by consistently applying a systematic process across all research questions.
5. LEGEND will generate evidence using best practices.
6. LEGEND will include empirical evaluation through the use of control questions.
7. LEGEND will generate evidence using open-source software that is freely available to all.
8. LEGEND will not be used to evaluate new methods.
9. LEGEND will generate evidence across a network of multiple databases.
10. LEGEND will maintain data confidentiality; patient-level data will not be shared between sites in the network.
LEGEND in practice

Figure 2. Comparisons of single-drug hypertension treatments in randomized controlled trials (left) and in LEGEND (right). Each circle represents an ingredient. Color groupings indicate drug classes. A line between circles indicates the 2 drugs are compared in at least 1 study.
LEGEND has produced a new model for generating reliable evidence and new opportunities for collaborative research.

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

Research and Applications
Large-scale evidence generation and evaluation across a network of databases (LEGEND): assessing validity using hypertension as a case study

Comparative First-Line Effectiveness and Safety of ACE (Angiotensin-Converting Enzyme) Inhibitors and Angiotensin Receptor Blockers: A Multinational Cohort Study
Large-scale evidence through large-scale collaboration

March 2022

Original Investigation | Cardiology
Analysis of Dual Combination Therapies Used in Treatment of Hypertension in a Multinational Cohort

Yuan Lu, ScD; Mui Van Zward, BS; Yun Liu, PhD; Jing Li, MS; Xiaolin Wang, MS; Yong Chen, PhD; Zhengfeng Chen, MBBS, MMed; Jaehyeong Cho, PhD; Sreemaneer Raj Dorajoo, PhD; Mengjia Feng, PhD; Min Huei Hsu, MD, PhD; Jason C. Hu, PhD; Usman Iqbal, PharmD, MBA, PhD; Jitendra Jonnagaddala, PhD; Yu-Chuan Li, MD, PhD; Siaw-Teng Liaw, MBBS, PhD; Hong-Seok Lim, MD, PhD; Xee Yuan Ngiam, MBBS, MMed; Phung Anh Nguyen, PhD; Rae Woong Park, MD, PhD; Nicole Pratt, PhD; Christian Reich, MD, PhD; Sang Youl Rhee, MD; Selva Muthu Kumaran Sathappan, MSc; Seo Jeong Shin, PhD; Hui Xing Tan, M Tech; Seng Chan You, MD; Xin Zhang, MS; Harlan M. Krumholz, MD, SM; Marc A. Suchard, MD, PhD; Hua Xu, PhD

Abstract

IMPORATANCE More than 1 billion adults have hypertension globally, of whom 70% cannot achieve their hypertension control goal with monotherapy alone. Data are lacking on clinical use patterns of dual combination therapies prescribed to patients who escalate from monotherapy.

OBJECTIVE To investigate the most common dual combinations prescribed for treatment escalation in different countries and how treatment use varies by age, sex, and history of cardiovascular disease.

DESIGN, SETTING, AND PARTICIPANTS This cohort study used data from 11 electronic health record databases that cover 118 million patients across 8 countries and regions between January 2000 and December 2019. Included participants were adult patients (ages ≥18 years) who newly initiated antihypertensive dual combination therapy after escalating from monotherapy. There were 2 databases included for 3 countries: the IQvias Longitudinal Patient Database (LPD) Australia and...

June 2022

BMJ Open

Large-scale evidence generation and evaluation across a network of databases for type 2 diabetes mellitus (LEGEND-T2DM): a protocol for a series of multinational, real-world comparative cardiovascular effectiveness and safety studies

Rohan Khera, MSc, FRCPath; Martin J Schuemie, PhD, FIBiol; Yuan Lu, PhD; Raj Jalan, MD; Ching-Chung Chu, MD, PhD; George Hripcsak, MD; Patrick B Ryan, PhD; Harlan M Krumholz, MD, SC; Marc A Suchard, PhD; David L Peterson, MD; Karen A Christiansen; Mark I Shrier; Kevin P Lannon; Paul A Solomon; Michal A Jaffe; Lisa R Heiss; David C Knowler; David Janni; Eric A Grossberg; Robin M Cohen; Patrick J McGaughey; June 2022

Key Points

Question What are the most common antihypertensive dual combinations prescribed to patients who escalate from monotherapy in clinical practice, and how do the combinations differ by country and patient demographic subgroup?

Findings In this cohort study of 970,335 individuals from 11 large databases, 12 dual combinations of antihypertensive drug classes were commonly used, with large variation...
OHDSI COVID-19 Study-a-Thon (Mar2020)
Findings:

- Patients hospitalized with COVID are systematically different from those hospitalized with flu
- COVID hospitalized patients, when compared those hospitalized for influenza:
  - Greater proportion are male and slightly younger
  - Fewer comorbidities and lower medication use
- Utilized claims and electronic medical records from 10 databases across 3 different countries
Large-scale characterization of COVID-19 disease natural history

Together, OHDSI has studied:

- **>17.2m** patients tested for SAR-CoV-2
- **>4.5m** patients diagnosed or tested positive for COVID-19
- **>890k** patients hospitalized with COVID-19
Large-scale characterization of COVID-19 disease natural history

Characteristics and outcomes of patients with COVID-19 with and without prevalent hypertension: a multinational cohort study

Carlen Reyes, Andrea Pistillo, Elena Roel, Diana Puente, Thamar M Alshammari, Waheed-Ui-Rahman Ahmed, Heba Alghouli, Carlos Areli Neus Valverde, Gabriel de Mae Jordi Martinez Roldan, Immaci Aslih Golozar, Christian Rei, Seng Chan You, Kristine Elyn Fredrik Nyberg, Anna Ostropo, Marc A. Suchard, Patrick Rear

International Journal of Obesity

Thirty-Day Outcomes of Children and Adolescents With COVID-19: An International Experience

Talita Duarte-Salles, PhD,a David Vezzaya, PhD,a Andrea Pistillo, MS,ca Paula Casajust, MSC,b Anthony G. Sema, PhD, a Lina Yih Hui Lai, MDb, Albert Prats-Uribe, MD,a Waheed-Ul-Rahman Ahmed,a Heba Alghouli,a Thamar M. Alshammari,a Edward Burn,a David Chan Yoo, PhD,a Elear Blacketer, MPH,a Scott Duvall,a Thomas Falconer, MSc,a Sergio Fernandez-Bertolín, Dr.c Stephane Aslih Golozar, PhD,a Mengchung Gong, PhD,a Eng Hooi Tan, PhD,a Yotcho Hoser, PhD,a Fabio Vells,d, PhD,a Daniel R. Morales, PhD,a Fredrik Nyberg, PhD,a Jose D. Posada, PhD,a Martina Recalde, MSc,b Elena Roel,b Lisa M. Schilling, PhD,a Nigam H. Shah, PhD,a Karimsha Shah, PhD,a Mari A. Suchard, PhD,a Lin Zhang, PhD,a Yong Zhand, PhD,a Andrew E. Williams, PhD,a Christan G. Reich, PhD,a Georgio Hricpca, PhD,a Peter Rijnbeek, PhD,a Patrick Ryan,a Kristin Koskia, MPH,a Daniel Prieto-Alhambra, PhD,a

RHEUMATOLOGY

COVID-19 in patients with autoimmune diseases: characteristics and outcomes in a multinational network of cohorts across three countries

Eng Hooi Tan,a Anthony G. Sema,a Albert Prats-Uribe,a Seng Chan You,a Waheed-Ul-Rahman Ahmed,a Kristin Koskia,a Christan Reich,a Scott L. Duval,a Kristine Elyn Lynch,a Michael E. Matheny,a Talita Duarte-Salles,a Sergio Fernandez-Bertolín,a George Hricpca,a Karthik Natarajan,a,b Thomas Falconer,a Matthew Spotnitz,a Ano Ostropo,a,b Claire Blacketer,a,b Thamar M. Alshammari,a Heba Alghouli,a Nigam H. Shah,a Jennifer C. E. Lane,a Dalia M. Dawoud,a Karimsha Shah,a Yue Yang,a Lin Zhang,a,c,d,c Carlos Arelia,a,b,Aslih Golozar,a,b,c Martina Recalde,a,b,c Paula Casajust,a,b,c Jitendra Jonnagaddala,a,b,c Vignesh Subbian,a,b,c David Vezzaya,a,b,c Lana Y. H. Lei,a Fredrik Nyberg,a Daniel R. Morales,a Jose D. Posada,a Nigam H. Shah,a Mengchung Gong,a Arani Vivekananthan,a Aaron Abend,a Evan P. Minty,a Marc Suchard,a Peter Rijnbeek,a Patrick B. Ryan,a and Daniel Prieto-Alhambra,a

CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION | RESEARCH ARTICLE
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.
Use of repurposed and adjuvant drugs in hospital patients with covid-19: multinational network cohort study


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 authorization
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
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.
Objective: develop and externally validate **COVID-19 Estimated Risk** scores that quantify a patient’s risk of hospital admission, hospitalization requiring intensive services or fatality.
• COVER interactive website to provide live risk scores

• Impact: Health minister of Catalonia Spain explicitly mentions the COVER index as one of the indicators they will use to measure the impact of a given outbreak.
COVER: COVID risk prediction

Interactive application for exploring prediction:

- [https://data.ohdsi.org/Covid19CoverPrediction/](https://data.ohdsi.org/Covid19CoverPrediction/)

Learning and establishing Patient-Level Prediction best practices

A standardized analytics pipeline for reliable and rapid development and validation of prediction models using observational health data.
COVID-19 Vaccine Adverse Events of Special Interest

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

Xintong Li, Anna Ostropole, Rupa Makadia, Azza Shoabii, Gowtham Rao, Anthony G Sena, Eugenia Martinez-Hernandez, Antonella Delmestri, Katia Verhamme, Peter R Rijnbeek, Talita Duarte-Salles, Marc A Suchard, Patrick B Ryan, George Hripcsak, Daniel Prieto-Alhambra

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

Medicines Agency

BMIs safety committee, P&RC, concluded its preliminary review of a signal of blood clots in people vaccinated with Vaccinovirus (previous 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 EUA 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 AESI motivated further phenotype development and incidence research

Factors Influencing Background Incidence Rate Calculation: Systematic Empirical Evaluation Across an International Network of Observational Databases

Anna Ostropolets, Yixue Qi, Xiaoyan Wang, Xiaoyu Jiang, and Jan O. Rosing

Phenotype Algorithms for the Identification and Characterization of Vaccine-Induced Thrombotic Thrombocytopenia in Real World Data: A Multinational Network Cohort Study


Characterizing Anchoring B Comparator Selection Due to COVID-19 and Influenza

Anna Ostropolets, Patrick B. Ryan, and Martijn

Published on 17.6.2022 in Vol 8, No 6 (2022): June
Preprints (earlier versions) of this paper are available at https://preprints.jmir.org/2021.
Evaluating performance of vaccine safety surveillance methods: EUMAEUS

EUMAEUS: Evaluating Use of Methods for Adverse Event Under Surveillance (for vaccines)

Version: 1.2.0

1 List of Abbreviations

AUC: Area Under the receiver-operator Curve
CCAE: Common Commercial Experiences
CCMS: Coordinating Committee for International Organizations of Medical Sciences
COVID-19: Coronavirus Disease 2019
COVID-19 Surveillance Dashboard 2019
CPRE: Clinical Practice Research Datalink
CREN: Comprehensive R Archive Network
EHM: Electronic Health Record
EMA: European Medicines Agency

Bias, Precision and Timeliness of Historical (Background) Rate Comparison Methods for Vaccine Safety Monitoring: An Empirical Multi-Database Analysis

Xintong Li\(^1\), Lena YH Li\(^2\), Anna Ostromp\(^3\), Fazlizah Arshad\(^4\), Eng Hock Tan\(^5\), Pauline Cawajir\(^6\), Thaneir M. Abhammar\(^7\), Tafida Danso-Salifu\(^8\), Brian P. Merry\(^9\), Carlos Arria\(^10\), Nicola Post\(^11\), Patricia B. Ryan\(^12\), George Mpakalita\(^11\), Marc A. Suchard\(^15,16\), and Daniel Preto-Alhamara\(^13,14\)

\(^1\)Center for Statistics in Medicine, NCPPM, University of Oxford, United Kingdom, \(^2\)School of Medical Sciences, University of Manchester, Manchester, United Kingdom, \(^3\)Department of Biostatistics, Columbia University, New York, \(^4\)United States, \(^5\)Department of Biostatistics, University of California, Los Angeles, California, United States, \(^6\)World Health Organization, Thrissur, Kerala, India, \(^7\)School of Public Health, University of California, Los Angeles, California, United States, \(^8\)Departments of Obstetrics and Gynecology, University of Barcelona, Barcelona, Spain, \(^9\)WHO Collaborating Centre for Polio Vaccine Safety, WHO Collaborating Centre for Vaccine Safety, WHO Collaborating Centre for Vaccine Safety, \(^10\)Healthcare Delivery, University of California, Los Angeles, California, United States, \(^11\)FDA, \(^12\)Canadian Institutes of Health Research, \(^13\)National Institutes of Health, \(^14\)Institute of Translational Medicine, \(^15\)Boston Children’s Hospital, \(^16\)University of Oxford.

Table 1: Metrics based on the effect size estimate (e.g. hazard ratio or odds ratio), using 50 negative and 50 positive controls. This includes all negative controls, including those that were not powered to be used for positive control synthesis.
OHDSI2020 Symposium (virtual)

https://www.ohdsi.org/2020-ohdsi-global-symposium/
OHDSI2021 Symposium (virtual)

Day 3 • Tuesday, Sept. 14

Main Symposium
Plenary: OHDSI Impact on the COVID-19 Pandemic
8 am - 7 pm (ET)
The first of the two main symposium days, the Sept. 14 session will open at 8 am ET with the annual State of the Community Address; if you signed up for the special OHDSI surprise, you’ll want to have it for this session (if you didn’t, you will still be able to follow along). That will be followed by our first plenary session and our first Collaborator Showcase session. Make sure you check out the section about the Collaborator Showcase on this page below.

8 am ET: State of the Community Address
9 am ET: Plenary Session (OHDSI Impact on the COVID-19 Pandemic)
11 am ET: Reaction Panel
1 pm ET: Collaborator Showcase
5 pm ET: Networking Session

OHDSI2021 Symposium is on gather.town!

Join our virtual community!

Day 4 • Wednesday, Sept. 15

Main Symposium
Interactive Plenary: Generating Reliable Evidence
3 am - 5 pm (ET)
The second of the two main symposium days, the Sept. 15 session will open at 3 am ET with the second Collaborator Showcase session, the two sessions are being held at different times to encourage collaborators around the world to take part. More information on this is below. The second plenary session will follow at 8 am ET, and it will be an interactive session building off of the Day 2 workshop. The closing session, which will include Titan Award announcements, will follow, and then there will be a second networking session.

3 am ET: Collaborator Showcase
8 am ET: Interactive Plenary Session (Generating Reliable Evidence)
11:30 am ET: Closing Session (Includes Titan Award announcements)
12 pm ET: Networking Session

https://www.ohdsi.org/2021-ohdsi-global-symposium/
Phenotype Phenotype • Daily Threads & What We Learned

"Phenotype Phebruary" was a community-wide initiative to both develop and evaluate phenotypes for health outcomes that could be investigated by the community. Patrick Ryan introduced this initiative in both a video presentation and a forum post, and each of the conversations around the “28 phenotypes for 28 days” are being held within the OHDSI forums.

This page will provide direct links to each forum post, which is where conversations around each specific phenotype should be held. The video on the right includes "phun phacts" shared about each phenotype during our weekly community calls.

Daily Phenotype Phebruary Links

(Future dates are subject to changes)

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

https://www.ohdsi.org/phenotype-phebruary/
OHDSI DevCon 2022 Welcomes & Mentors New Contributors To Our Open-Source Environment

Watch All Eight Workshops, Talks & The Panel From DevCon Below

The Open-Source Community hosted the first DevCon on Friday, April 22 as a way of accepting and mentoring new contributors to our environment. Organized by Paul Nagy and Adam Black, the event included eight workshops, talks, and a panel discussion to both welcome and engage both current and future developers within OHDSI.

All videos from this session have or will be uploaded to this page. A big announcement from DevCon was the formation of the Khron Contributor Cohort, which will help onboard and mentor open-source developers in the community. If you are interested in joining the effort, please fill out the application.

To learn more about the Khron Contributor Cohort, please check out the State of the Open Source Community presentation below.

State Of The Community Presentation

Panel: Putting The Pieces Together

https://www.ohdsi.org/devcon2022/
OHDSI Workgroups have expanded

- **ATLAS**
  - Current Participants: 56
  - Lead: Anthony Sena

- **Clinical Trials**
  - Current Participants: 107
  - Leads: Mike Hamidi, Lin Zhen

- **Common Data Model**
  - Current Participants: 241
  - Lead: Clair Blacketer

- **OHDSI Steering Committee**
  - Current Participants: 24
  - Lead: Patrick Ryan

- **Oncology**
  - Current Participants: 123
  - Lead: Shilpa Ratwani

- **Data Quality Dashboard Development**
  - Current Participants: 90
  - Lead: Clair Blacketer

- **Early-Stage Researchers**
  - Current Participants: 44
  - Leads: Faaziah Arshad, Ross Williams

- **Education**
  - Current Participants: 21
  - Lead: Nigel Hughes

- **Pharmacovigilance Evidence Investigation**
  - Current Participants: 48
  - Leads: Rich Boyce, Erica Voss

- **OHDSI**
  - Current Participants: 88
  - Leads: Gowtham Rao

- **Phenotype Development & Evaluation**
  - Current Participants: 88
  - Leads: Gowtham Rao

- **Population-Level Effect Estimation**
  - Current Participants: 152
  - Lead: Martijn Schuemie, Marc Suchard

- **OHDSI Asia-Pacific (APAC)**
  - Current Participants: 38
  - Lead: Mul VanZandt

- **Patient-Generated Health Data**
  - Current Participants: 76
  - Lead: Seng Chan You

- **OHDSI APAC Steering Committee**
  - Current Participants: 29
  - Lead: Mul VanZandt

- **Health Equity**
  - Current Participants: 43
  - Lead: Jake Gilberg

- **Latin America**
  - Current Participants: 14
  - Lead: Jose Posadas

- **Medical Devices**
  - Current Participants: 50
  - Leads: Vojoosh Huser, Asyiah Lin

- **Psychiatry**
  - Current Participants: 64
  - Lead: Shilpa Ratwani

- **Natural Language Processing**
  - Current Participants: 228
  - Lead: Hui Xu

- **HADES (Health Analytics Data-to-Evidence Suite)**
  - Current Participants: 112
  - Lead: Martijn Schuemie

- **Patient-Level Prediction**
  - Current Participants: 152
  - Lead: Jenna Reps, Peter Rijnbeek

- **Registry (formerly UK Biobank)**
  - Current Participants: 55
  - Lead: Maxim Moinal

- **Medical Devices**
  - Current Participants: 26
  - Lead: Patrick Ryan

- **Women of OHDSI**
  - Current Participants: 97
  - Lead: Maura Beaton

- **Vaccine Safety**
  - Current Participants: 35
  - Lead: Adam Black

- **Vaccine Vocabulary**
  - Current Participants: 35
  - Lead: Adam Black

https://www.ohdsi.org/ohdsi-workgroups/
Community calls offer weekly collaboration

June 29: EUMAEUS Presentation
- Evaluating Use of Methods for Adverse Event Under Surveillance
- Literature review
- Overview of the EUMAEUS Experiment Design
- Bias, precision and timeliness of historical rate comparison methods
- Combining Methods in a Safety Surveillance System

May 11: OHDSI Debates
- Estimation for Two-Dose Vaccines
- Comparison of Performance across methods

June 22: Community Brainstorm on Health Equity Discussion Moderators
- Noémi Elhadad
- Jake Gilberg
- Jody-Ann McGegon

June 8: 10-Minute Tutorials
- PHOEBE: Area 3 Data Playoff: PhD Students, Columbia University Dept. of Biomedical Informatics
- Cohort Diagnostics: Jonathan Thibault
- ATC Hierarchy: Christine Ratel

May 18: Prostate Cancer Study Report

April 6 Community Call OHDSI Studies
- Cancer Risk Between 11 Studies
- Alpha 1 for Reducing Informational Bias (pills) study

March 23 Community Call Topic
- OHDSI Collaboration with FDA Best Program
- FDA BEST Overview, Research Method Development – Evidence Rates for Vaccine Safety
- Methods Development – Small Sample Meta-Analysis, EUMAEUS
- FDA Workshops and Seminar Series
- Training and Engagement

March 16 Community Call Topic: Advances In Patient-Level Prediction
- Best Practices for Prediction Using Observational Data
- External Validation of Existing Dementia Prediction Models on Observational Health Data
- The Prediction Model Library

March 2 Community Call Topic: Breakout Sessions
- ATLAS
- ETL
- HADES

April 20 Community Call Topic: Local Impacts of OHDSI
- Stanford University
- University of Colorado Denver
- Columbia University

https://ohdsi.org/ohdsi-community-calls/
Collaborating to establish international data standards

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 data when and where they need it.”

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. This cornerstone has global implications with the potential to permit the clinical community to define the elements they need, package and share them in a consistent single structure.

“We are excited to have the OHDSI community join this partnership with HL7 to evolve community standards around observational research and clinical care,” said George Hripcsak, MD, MS, OHDSI’s coordinating center director. “These standards set the foundation for our mission of global, open-scientific research, and this partnership will accelerate the development of effective and safe treatments for diseases facing today’s global population.”

About Health Level Seven International (HL7)

Founded in 1987, Health Level Seven International is the global authority for healthcare information interoperability and standards with affiliates established in more than 36 countries. HL7 is a non-profit, ANSI accredited standards development organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7’s members represent approximately 600 corporate members, which include more than 90 percent of the information systems vendors serving healthcare. HL7 collaborates with other standards developers and provider, payer, philanthropic and government agencies at the highest levels to ensure the development of comprehensive and reliable standards and successful interoperability efforts.

https://www.ohdsi.org/ohdsi-hl7-collaboration/
Establishing agreements to enable community to apply open data standards and content

“Through the collaboration, SNOMED CT will be available to all OHDSI users for use in its products. Additionally, SNOMED International will work with OHDSI to provide SNOMED CT Development Licenses to users in non-member countries.”

EHDEN Academy provides robust educational content to OHDSI community and beyond

- 18 courses
- >1,800 users from >60 countries
- >790 completions of ‘Getting Started’

https://academy.ehden.eu/
OHDSI partners collaborating to support EMA through DARWIN-EU

Initiation of DARWIN EU® Coordination Centre advances integration of real-world evidence into assessment of medicines in the EU

News 09/02/2022

EMA is initiating today the establishment of the Coordination Centre for the Data Analysis and Real World Interrogation Network (DARWIN EU®).

The role of the Coordination Centre is to develop and manage a network of real-world healthcare data sources across the EU and to conduct scientific studies requested by medicines regulators and, at a later stage, requested by other stakeholders.

The vision of DARWIN EU® is to give EMA and national competent authorities in EU Member States access to valid and trustworthy real-world evidence, for example on diseases, patient populations, and the use, safety and effectiveness of medicines, including vaccines, throughout the lifecycle of a medicinal product.

By supporting decision-making on the development, authorisation and surveillance of medicines, a wide range of stakeholders will benefit, from patients and healthcare professionals to health technology assessment bodies and the pharmaceutical industry. Additionally, DARWIN EU® will provide an invaluable resource to prepare for and respond to future healthcare crises and pandemics.

For example, the availability of timely and reliable real-world evidence can lead to innovative medicines becoming more quickly available to patients. Better evidence also supports more informed regulatory decision-making on the safe and effective use by patients of medicines on the market.

EMA will be working with Erasmus University Medical Center Rotterdam to establish the DARWIN EU® Coordination Centre. The contract was awarded to Erasmus University Medical Center Rotterdam following a call for tender for a service provider published in June 2021. The contractor will set up the necessary
Where are we today at the 2022 in-person European OHDSI Symposium?
Where we are today: European OHDSI Symposium June2022

• Community publishing impactful work on data standards, methods research, and clinical applications (>250 publications since 2018)
• >8,000 citations of OHDSI research in other publications + EMA + UpToDate ...

• Community education resources are actively used, with >370 hours of video content, which has now been cumulatively watched for >184,000 hours as of Jun2022

• Community continues to accelerate in its growth, now with >1,500 different co-authors contributing to OHDSI-related research
Thank you Paul Nagy for developing the OHDSI community dashboard!

Welcome to the OHDSI Community Dashboard

Observational Health Data Sciences and Informatics (OHDSI) is an open science community. OHDSI’s mission is to improve health by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care. The OHDSI Community Dashboard is a tool to highlight the progress we are making toward this mission and the collective accomplishments and impact of our community. A goal of the dashboard is help our community identify how members can see the OHDSI eco-system as an interconnected system to make a larger impact. We hope you find these tools useful staying up to date with all the activities in OHDSI as well as finding new colleagues in our community to collaborate with. Dashboards are developed to represent various aspects of the OHDSI community activities.

Publication dashboard: PubMed Publication Tracking highlights scholarship generated the using OMOP Common Data Model, OHDSI tools, or the OHDSI network.

http://dash.ohdsi.org/
Where we were at Mar2019

- Community publishing useful work, primarily methodological research (reached 20 papers in 2018)
- Those papers now widely cited (>6,000 times as of Jun2022)

- Community education resources started to grow, with >25 hours of video content per year, which has now been cumulatively watched for >75,000 hours as of Jun2022

- Community was growing nicely, >500 different authors with work related to OHDSI research by end of 2018
Where we are today: June 2022

- Community publishing impactful work on data standards, methods research, and clinical applications (>250 publications since 2018)
- >8,000 citations of OHDSI research in other publications + EMA + UpToDate ...
- Community education resources are actively used, with >370 hours of video content, which has now been cumulatively watched for >184,000 hours as of Jun 2022
- Community continues to accelerate in its growth, now with >1,500 different co-authors contributing to OHDSI-related research
A Cruise Around the OHDSI Europe Community

Nigel Hughes
Janssen Research and Development
EHDEN
A Cruise Around the OHDSI Europe Community

1. **Estonia.** Conversion of Estonian health data into the OMOP CDM
2. **Finland.** The Finnish OMOP data network (FinOMOP)
3. **Denmark.** Transforming Danish Registries to the OMOP Common Data Model: use case on the Danish Colorectal Cancer Group (DCCG) Database
4. **Norway.** Norwegian registries onto OMOP Common Data Model: mapping challenges and opportunities for pregnancy studies
5. **Germany.** OHDSI Germany: A recap after one year
6. **Italy.** The Italian national node of OHDSI Europe
7. **Greece.** An update from the Greek National Node
8. **Ukraine.** Integration prospects of the Ukrainian healthcare system with OMOP CDM
9. **Israel.** The journey from isolated EHR’s to unified CDM network
10. **France.** The Health Data Hub, the French national gateway for an easy, unified, transparent and secure access to health data
Conversion of Estonian health data into the OMOP CDM

Marek Oja
Institute of Computer Science, University of Tartu
Conversion of Estonian health data into the OMOP CDM

insurance claims, prescription data and electronic health records

Marek Oja PhD
University of Tartu
STACC
Estonia

Population of 1.4 million

Digital health data for most of the population from national registries
Estonian healthcare system

Healthcare providers

~800 primary care providers

20 hospitals

~600 private care Providers (mostly dental care)

National health databases

• insurance claims
• digital prescriptions
• electronic health records
• cancer registry
• death registry
• etc.

Mandatory reporting
Three data sources

● **Electronic health records**
  ○ **Measurements** together with measurement values (LOINC, etc.)
  ○ **Cancer** specific measurements and clinical findings
  ○ **Pathology** findings
  ○ Diagnoses (ICD10)

● **Digital Prescriptions**
  ○ Prescribed and dispensed **drugs** (ATC code, package code)
  ○ Diagnoses (ICD10)

● **Insurance claims**
  ○ **Services** and **treatments** performed (local codes and NCSP to SNOMED)
  ○ Diagnoses (ICD10)
Combining three data sources into one CDM - reusable ETL process

SQL & shell scripts for:
- Setting up schemas for OMOP CDM
- Building local copy of OMOP Vocabulary
- Building mapping tables
- Converting data to OMOP CDM

Cleaning of raw data  
ETL process  
Validation
Applications

● Following datasets in OMOP format in University of Tartu:
  ○ 10% random population in Estonia (RITA-MAITT)
  ○ Asthma specific dataset
  ○ COVID specific dataset
  ○ Estonian Biobank health data

● Participated in network studies
  ○ Prostate cancer study (PIONEER)
  ○ Adverse Events of Special Interest within COVID-19 Subjects
  ○ EHDEN Asthma drug utilization study

● Local studies
  ○ HPV (human papillomavirus) prevalence in Estonia
  ○ Cardiovascular risk estimation
  ○ Many MSc and BSc theses
Acknowledgements

Team:  
Jaak Vilo  
Sulev Reisberg  
Sven Laur  
Raivo Kolde  
Marek Oja  
Sirli Tamm

PhD students:  
Ida Maria Orula  
Maarja Pajusalu  
Harry-Anton Talvik  
Markus Haug  
Hendrik Šuvalov

This work was supported by the Estonian Research Council grants number PRG1095, RITA1/02-96; the European Union through the European Regional Development Fund grant number EU48684; and the European Social Fund via IT Academy programme. The whole conversion was carried out in the High Performance Computing Center of the University of Tartu.
Thank you!
The Finnish OMOP data network (FinOMOP)

Javier Gracia-Tabuenca
FinnGen
Who we are

University Hospitals

- Sampo Kukkurainen
- Toni Mikkola
- Tarja Laitinen
- Leena Hakkarainen
- Anna Hammais
- Pia Tajanan
- Juha-Matti Varjonen
- Otto Ettala
- Perttu Koskenvesa
- Kimmo Porkka
- Annu Kaila
- Otso Peippo
- Ilona Siljander
- Oscar Brück
- Simo Ryhänen
- Eric Le Tortorec
- Arto Vesterbacka

SMEs

- Max Salmi
- Kalle Kollin
- Juha Koski
- Pasi Rikalainen
- Anna Virtanen

National health institute

- Finnish institute for health and welfare
- Persephone Doupi
- Arto Vuori
- Jan Magnusson

Research Projects

- Javier Gracia-Tabuenca
- Sam Padmanabhuni
Where we are

17 Vocabularies to OMOP

<table>
<thead>
<tr>
<th>Vocabulary</th>
<th>Mapping progress</th>
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<tbody>
<tr>
<td>FHIL</td>
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<td>HPN</td>
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<td>ICD9R</td>
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<td></td>
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<tr>
<td>LABS_turku</td>
<td></td>
</tr>
<tr>
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<td>NCPRM</td>
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<td>REINB</td>
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<td>SPAT</td>
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<td>UNITR</td>
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<tr>
<td>MEOSPECERI</td>
<td></td>
</tr>
<tr>
<td>MICROBEI</td>
<td></td>
</tr>
<tr>
<td>ProcedureModifer</td>
<td></td>
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</tbody>
</table>

4 Databases to OMOP-CDM v5.3.1

<table>
<thead>
<tr>
<th></th>
<th>Person</th>
<th>Visit</th>
<th>Condition</th>
<th>Procedure</th>
<th>Drug</th>
<th>Measur.</th>
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<td>9M</td>
<td>3.7M</td>
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<td>Helsinki Hospital</td>
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<td>157M</td>
<td>87M</td>
<td>6M</td>
<td>104M</td>
<td>297K</td>
</tr>
</tbody>
</table>

Use cases

- 1 national federated analyses: Acute leukemia
- Local use case: Atlas is regularly used to case-control cohorts for running genome wide association studies (GWAS), in Finngen.
Where we are going

- Participate in international federated analysis
- Vocabularies from STCM to C&CR [2]
- National federated analysis
- ETL 2 more databases:
  - Kuopio University Hospital,
  - Pilot in THL (National health institute) = all hospitals combined
- Building tools
  - Shiny app to visualize cohorts [1]
  - Shiny app quick analyses in local data
  - Dashboard to visualize mapping progress [poster]

The table on the right summarizes the current status of the FinOMOP mapping repository. Each row shows a **vocabulary**, if it is maintained by OMOP, FinOMOP, or OMOP+FinOMOP for a combination of both. **Mapping progress** shows the proportion of codes in a vocabulary that have been mapped to one or more OMOP-standard concepts.

Following columns show how well the vocabulary covers the events in different databases. Last column is a combination of all the databases. A code used in a clinical event may fall in one of the following categories:

- **Events with standard code**: the code exist in the target vocabulary and is mapped to an OMOP-standard concept.
- **Events with non-standard code**: the code exist in the target vocabulary but is not yet mapped to an OMOP-standard concept.
- **Events with not found code**: the code do not exist in the target vocabulary.

Exactly what events fall in each category can be explored by selecting the vocabulary’s tab over the main table.

### Description

The table on the right summarizes the current status of the FinOMOP mapping repository. Each row shows a **vocabulary**, if it is maintained by OMOP, FinOMOP, or OMOP+FinOMOP for a combination of both. **Mapping progress** shows the proportion of codes in a vocabulary that have been mapped to one or more OMOP-standard concepts.

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Exactly what events fall in each category can be explored by selecting the vocabulary’s tab over the main table.
Transforming Danish Registries to the OMOP Common Data Model: use case on the Danish Colorectal Cancer Group (DCCG) Database

Andi Tsouchnika

Center for Surgical Science, Zealand University Hospital
Transforming Danish Registries to the OMOP Common Data Model: use case on the Danish Colorectal Cancer Group (DCCCG) Database
Clinical Motivation

Registry Data
- Patient profile
- Key Outcomes

New patient
- Prediction models

Decision
- Prehabilitation
- Revised surgery
- Oncological treatment
- Medical treatment
- No treatment

Decision process:
1. Registry Data
2. New patient
3. Prediction models
4. Decision
Data curation & De-identification

### Source Data

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<tr>
<th>CPR</th>
<th>Cancer</th>
<th>DiagDate</th>
<th>Age</th>
<th>Blood</th>
</tr>
</thead>
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<td>2010-12-07</td>
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<td>305</td>
</tr>
</tbody>
</table>

### Data Curation

1. Invalid dates
2. Invalid values (illogical values, formats)

<table>
<thead>
<tr>
<th>CPR</th>
<th>Cancer</th>
<th>DiagDate</th>
<th>Age</th>
<th>Blood</th>
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<td>305</td>
</tr>
</tbody>
</table>

### De-identification

1. Hash direct identifiers
2. Remove infrequent values
3. Person date shift
4. Combine infrequent ages
5. Modify phys. meas.

<table>
<thead>
<tr>
<th>CPR</th>
<th>Cancer</th>
<th>DiagDate</th>
<th>Age</th>
<th>Blood</th>
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<tbody>
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<td>240912</td>
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<td>302</td>
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<td>2014-05-08</td>
<td>75</td>
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<tr>
<td>200899</td>
<td>03</td>
<td>2013-12-17</td>
<td>46</td>
<td>303</td>
</tr>
</tbody>
</table>

### Quality Control

- Statistical comparison
- Medical Evaluation
- Logging review

- Invalid dates in column: '{}', in {} DC1 check.
- Invalid values in column: '{}', in {} DC2 check.
- Seldom entries in column: '{}', in De-ID 2.
- Total rows affected by age shift in De-ID 4.
- Outliers in column: '{}', in De-ID 5.
OMOP Common Data Model

De-identified

<table>
<thead>
<tr>
<th>EHR</th>
<th>De-Id</th>
<th>Engine</th>
<th>Age</th>
<th>Brand</th>
</tr>
</thead>
<tbody>
<tr>
<td>1234</td>
<td>65</td>
<td>JPM</td>
<td>70</td>
<td>302</td>
</tr>
<tr>
<td>9876</td>
<td>42</td>
<td>HS</td>
<td>75</td>
<td>300</td>
</tr>
<tr>
<td>5678</td>
<td>2001-12-17</td>
<td>65</td>
<td>JPM</td>
<td></td>
</tr>
</tbody>
</table>

Content mapping

- Community discussions
- Clinical review/validation
- Mapping consistency
- Incomplete mappings
- Erroneous mappings
- Guideline conformance

Structural

- THEMIS conventions
- Logic Inconsistencies
- Incomplete logic
- Corrupt relational logic

OMOP CDM v5.3

Quality Control

- Statistical comparison
- Single-patient comparison

Logging review

- Replaced {} alternative dates for column {}  
- Created visits for {} rows going through column {}  
- {} care sites could not be correctly mapped  
- Dropped {} rows because of value type = Missing

Data Quality Dashboard

OMOP ETL

Extract Transform Load

OMOP ETL
OMOP CDM Results

<table>
<thead>
<tr>
<th>TABLENAME</th>
<th>COUNT</th>
<th>PATIENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>observation</td>
<td>5,124,260</td>
<td>76,849</td>
</tr>
<tr>
<td>condition_occurrence</td>
<td>1,169,054</td>
<td>76,849</td>
</tr>
<tr>
<td>measurement</td>
<td>1,079,371</td>
<td>76,847</td>
</tr>
<tr>
<td>condition_era</td>
<td>878,790</td>
<td>76,849</td>
</tr>
<tr>
<td>procedure_occurrence</td>
<td>750,378</td>
<td>74,557</td>
</tr>
<tr>
<td>visit_occurrence</td>
<td>308,406</td>
<td>76,849</td>
</tr>
<tr>
<td>specimen</td>
<td>139,465</td>
<td>40,479</td>
</tr>
<tr>
<td>observation_period</td>
<td>76,849</td>
<td>76,849</td>
</tr>
<tr>
<td>person</td>
<td>76,849</td>
<td>76,849</td>
</tr>
<tr>
<td>death</td>
<td>42,620</td>
<td>42,620</td>
</tr>
<tr>
<td>drug_era</td>
<td>8,784</td>
<td>4,953</td>
</tr>
<tr>
<td>drug_exposure</td>
<td>8,784</td>
<td>4,953</td>
</tr>
<tr>
<td>location</td>
<td>4,678</td>
<td>-</td>
</tr>
<tr>
<td>care_site</td>
<td>384</td>
<td>-</td>
</tr>
<tr>
<td>device_exposure</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>note</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>dose_era</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>cost</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>payer_plan_period</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>visit_detail</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>provider</td>
<td>0</td>
<td>-</td>
</tr>
</tbody>
</table>
Conclusion

- De-identification protocols can add to the ones already provided by the OMOP CDM and facilitate data authority compliance.

- Conversion to OMOP depends on date completeness and content coverage by standardized vocabularies, but offers the opportunity to medical experts to use standardized tools for complex cohorts and ML algorithms.

- Standard CDM quality tools guarantee conformity with community standards, but custom QC steps are required to ensure minimum loss of information.

- Producing a clinical-grade CDM that can be used for better patient care and personalized medicine requires detailed quality control processes.
CENTER FOR SURGICAL SCIENCE
Norwegian registries onto OMOP Common Data Model: mapping challenges and opportunities for pregnancy studies

Eimir Hurley
University of Oslo
Norwegian registries onto OMOP Common Data Model
mapping challenges and opportunities for pregnancy studies

What do we map at UiO?

- Medical Birth Registry of Norway (MBRN)
- Norwegian Prescription Database (NorPD)
- Norwegian Patient Registry (NPR)
- Norwegian Immunisation Registry (SYSVAK)
- Norwegian Surveillance System for Communicable Diseases (MSIS)

5.4 million inhabitants

Unique personal identifiers facilitating linkage between registries

Our journey started in October 2021

https://portal.ehden.eu/
UiO OMOP tables – v5.3.1

<table>
<thead>
<tr>
<th>OMOP Table</th>
<th>Row Counts</th>
</tr>
</thead>
<tbody>
<tr>
<td>'drug_exposure'</td>
<td>373'510'250</td>
</tr>
<tr>
<td>'measurement'</td>
<td>40'761'350</td>
</tr>
<tr>
<td>'observation'</td>
<td>38'190'803</td>
</tr>
<tr>
<td>'condition_occurrence'</td>
<td>13'572'671</td>
</tr>
<tr>
<td>'visit_occurrence'</td>
<td>6'186'120</td>
</tr>
<tr>
<td>'person'</td>
<td>5'508'030</td>
</tr>
<tr>
<td>'observation_period'</td>
<td>5'508'030</td>
</tr>
<tr>
<td>'fact_relationship'</td>
<td>3'658'561</td>
</tr>
<tr>
<td>'procedure_occurrence'</td>
<td>391'629</td>
</tr>
<tr>
<td>'death'</td>
<td>83'298</td>
</tr>
<tr>
<td>'provider'</td>
<td>47'981</td>
</tr>
</tbody>
</table>

5 508 030 individuals (2018-2020)
- 720 765 pregnancies
- 452 831 mothers
- 440 731 fathers
- 695 569 children
Concept mapping

- ATC codes => mapped automatically
- ICD-10 codes => mapped automatically
- 237 non-standard codes to standard concepts
  - 67 pregnancy related codes
  - 48 speciality related codes
  - 48 communicable disease related codes
  - 46 vaccine related codes
  - 17 drug related codes
  - 3 procedure related codes
- 40 custom concepts
  ⇒ many are relevant for pregnancy studies
## Creation of custom concepts (n=40)

Custom concepts: terminologies not supported by standard vocabularies

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPABORT_12</td>
<td>Previous miscarriages before 12 weeks of gestation</td>
<td>&lt;INTEGER&gt;</td>
</tr>
<tr>
<td>SPABORT_23</td>
<td>Previous miscarriages/stilbirths 12-23 weeks of gestation</td>
<td>&lt;INTEGER&gt;</td>
</tr>
<tr>
<td>PREEKLTIDL__1</td>
<td>Early preeclampsia</td>
<td>Yes</td>
</tr>
<tr>
<td>ROYK_FOER__2</td>
<td>Smoking before pregnancy</td>
<td>Sometimes</td>
</tr>
<tr>
<td>ROYK_FOER__3</td>
<td>Smoking before pregnancy</td>
<td>Daily</td>
</tr>
<tr>
<td>ROYK_BEG__1</td>
<td>Smoking at start of pregnancy</td>
<td>No</td>
</tr>
<tr>
<td>ROYK_BEG__2</td>
<td>Smoking at start of pregnancy</td>
<td>Sometimes</td>
</tr>
<tr>
<td>ROYK_BEG__3</td>
<td>Smoking at start of pregnancy</td>
<td>Daily</td>
</tr>
<tr>
<td>BLODNING_0500__1</td>
<td>Hemorrhage more than 500 ml during delivery</td>
<td>500-1500 mL</td>
</tr>
<tr>
<td>BLODNING_0500__2</td>
<td>Hemorrhage more than 500 ml during delivery</td>
<td>&gt;1500 mL</td>
</tr>
<tr>
<td>BLODNING_0500__3</td>
<td>Hemorrhage more than 500 ml during delivery</td>
<td>&gt;500 mL, unspecified</td>
</tr>
<tr>
<td>OVERFLYTTET__2</td>
<td>Child was transfered to neonatal ward</td>
<td>No</td>
</tr>
</tbody>
</table>
Lessons learnt from our mapping

✓ Norwegian registry data were successfully mapped onto OMOP CDM using OHDSI tools with high level of concordance

⇒ One in very few data partners with pregnancy data

✓ Several important pregnancy related variables could not be mapped with standard concepts

✓ A pregnancy extension table might be needed in future version of the OMOP CDM to support pregnancies studies
OHDSI Germany: A recap after one year

Michele Zoch
Technische Universität Dresden
OHDSI Germany
A recap after one year

Michele ZOCH, Elisa HENKE, Yuan PENG, Najia AHMADI, Joshua WIEDEKOPF, Mareike PRZYSUCHA, Josef SCHEPERS, Martin SEDLMAYR, Ines REINECKE
Where we started

Beginning

Today

Future

@ Dresden

Design for a Modular Clinical Trial Recruitment Support System Based on FHIR and OMOP

Ines Reinecke 1, Christian Gudien 2, Michele Kümmel 1, Azadeh Nassirian 1, Romina Blasini 3, Martin Sedlmayr 1

Affiliations + expand

PMID: 32570366  DOI: 10.3233/SHTI200142

Development of an ETL Process for Bulk and Incremental Load of German Patient Data into OMOP CDM Using FHIR

Authors: Elisa Henke, Yuan Peng, Ines Reinecke, Michele Zoch, Martin Sedlmayr

Our Goals

Beginning       Today       Future
Where we are right now

• Medication data
• Rare diseases
• Pre- and post-coordination
Where we want to go

- Overcoming administrative hurdles
- Onboarding of further participants in Germany
- Participating at international projects like DARWIN
- Collaborating in new projects
- Intensify joint work
We look forward to exchange and collaboration.

Michele Zoch
zoch@ohdsi.org

Ines Reinecke
reinecke@ohdsi.org

OHDSI Germany
The Italian national node of OHDSI Europe

Lucia Sacchi
University of Pavia
OHDSI Italia
Lucia Sacchi

Department of Electrical, Computer and Biomedical Engineering
University of Pavia, Italy
SIBIM (Italian Society for Biomedical Informatics)
30+ individuals
20 institutions
(14 data partners)
...and it's just the beginning!
Aims and objectives

• Promote OMOP/OHDSI
  o by dissemination events
  o adding new members and data partners to the node

• Promote national projects
  o ICT
  o Observational studies

• Coordinate dialogue with
  o Local Regions
  o Ministry of research and Ministry of health
  o Existing projects
Aims and objectives

- Contribute to the OHDSI community
- Mapping Italian terminologies and codes on OMOP
  - National codes: e.g. AIC codes for drugs (Federfarma)
  - Regional codes
- Define common administrative procedures
  - DPO approval
  - EC approval
  - AGID guidelines (for public entities)
  - Internal SOP / IO
Kick-off meeting
June 15th 2022

• 34 participants
First objective: the OHDSI Italia paper

- **Aim**
  - Run Achilles at each Data Partner involved
  
- **Steps**
  - Sep. 2022: DPIA
  - Dec. 2022: Protocol to the EC
  - Mar. 2023: Run Achilles
  - Jun. 2023:
    - merge results
    - prepare manuscript
An update from the Greek National Node

Pantelis Natsiavas
Centre for Research & Technology Hellas
An update for the Greek OHDSI|EHDEN node

Pantelis Natsiavas
Vlassios Dimitriadis
Greek National Node - status

• Already joined EHDEN
  • 2 data partners
  • 2 SMEs

• Joining process
  • Data partners: 6+ (have just submitted application for funding via EHDEN)
  • SMEs: 3 (starting certification process)
Challenges

Everybody is positive!

However...

• Lack of IT systems
• Lack of mentality
• Lack of central guidance in terms of policy
Communication plan

• Direct communication of the EHDEN|OHDSI rationale
  • Already communicated with more than 20 organizations (local pharma branches, research organizations, regional health authorities, hospitals, national data providers...).
  • More to come in the near future...

• Communication in organized events
  • Already communicated in 3 organized events (National event for ECRIN, ELEFI, association of clinical IT professionals etc.)
  • More to come in the near future... (conference organized in October from ELEFI etc.)

• Organize a dedicated half-day webinar
Action plan

• Organize pilot studies on Greek data nodes
  • Requires a critical mass of data providers, hopefully next year this will be in place
  • Perhaps based on already available protocol studies

• Organize Greek network meetings

• National research funding applications/proposals
#Join the Journey – in Greece (!!!)

Contact:
Pantelis Natsiavas, pnatsiavas@certh.gr
Vlassios Dimitriadis, blassid@certh.gr
Integration prospects of the Ukrainian healthcare system with OMOP CDM

Mariia Kolesnyk
SciForce
INTEGRATION PROSPECTS OF THE UKRAINIAN HEALTHCARE SYSTEM WITH OMOP CDM:

connecting and using ukrainian observational data by the global scientific community to improve the quality of medical services and the health of armed forces personnel and civilians during and after the war in Ukraine

CDM BENEFITS:
- SYNTACTIC AND SEMANTIC INTEROPERABILITY
- REUSABLE ANALYSIS
- COMPARABLE STUDIES
- REDUCED NEED TO REPROCESS SAME DATA MULTIPLE TIMES

In the context of Russia’s armed aggression against Ukraine, the introduction of data standardization is an urgent issue aimed at optimizing the provision of medical care to the military personnel and civilians, as well as collecting, processing, and summarizing data on the nature of injuries, provided medical help, the number of victims, killed, and disabled persons.

UKRAINIAN HEALTH STORES DATA IN THE FOLLOWING DATABASES (DB):
- Authorization DB
- Integration layer DB
- Master Patient Index DB
- Provider Relationship Management DB
- Data related to the Medical Events Data Structure in the Fast Healthcare Interoperability Resources (FHIR) standard

FULL INFORMATION IS AVAILABLE UNDER THE LINK

Scan QR to download the full paper

We developed a model for the potential ETL data conversion from the eHealth system to the OMOP CDM standard (v.8.4). It describes the main source tables and FHIR resources from the Ukrainian medical information systems (HIS) to the central ETL of eHealth and determines which of them can be used for the conversion to the OMOP CDM.

In the context of Russia’s armed aggression against Ukraine, the introduction of data standardization is an urgent issue aimed at optimizing the provision of medical care to the military personnel and civilians, as well as collecting, processing, and summarizing data on the nature of injuries, provided medical help, the number of victims, killed, and disabled persons.

UKRAINIAN MEDICAL INFORMATION SYSTEMS

10 MAIN SOURCE TABLES
- 50 SOURCE FIELDS
- OMOP CDM (V.8.4)
- FHIR RESOURCES
- model development
- eHealth website analysis https://health.gov.uk/

IMPLEMENTATION OF THE UKRAINIAN EHEALTH INTO THE OHDSI AND EHeden COMMUNITIES

Step 1: prepping and applying to become an EHeden data partner by the National Health Service of Ukraine.

Step 2: full-cycle data harmonization made by local certified small and medium-sized enterprises to maintain the Ukrainian economy.
The journey from isolated EHR’s to unified CDM network

Guy Livne
Israel Ministry of Health
Medical Center data-lake for research and innovation

The journey from isolated EHR’s to unified CDM network
The nature of Kineret (Hebrew name for the Sea of Galilee)

- Promoting research and innovation in health
  - 3 medical centers (9 by the end of 2023)
  - All range of hospital treatment and medical data
  - Diversity population
    - City & Rural area
    - All ages
    - Life-style
Oh, what a journey...

Encryption & anonymization modeling

NLP & text similarity model

MD doctors & Pharmacists

15%

Differences between hospitals in the network

Hebrew

Israel domestic coding

Directorate of Government Medical Centers, Israel

4M Patients

3M Patients

1M Patients
Accomplished and continue...

3 connected CDM’s
- Full EHR data
- All standard concepts
- 12M Visits, 15 years of patient history
Our team is in place and ready to go
The Health Data Hub, the French national gateway for an easy, unified, transparent and secure access to health data

Lorien Benda
Health Data Hub
The Health Data Hub’s mission: a unique national french gateway for easy, unified, transparent and secure access to health data

The uses of health data are multiplying and access to data sources in the shortest possible time is essential. The Health Data Hub is a public structure created at the end of 2019 to facilitate access to health data for public interest projects in order to improve the quality of care for patients.

- A **unique gateway** to health data in France
- A **collection of databases**, including one of the largest medico-administrative database in the world
- A **state-of-the-art and secure technological platform**
- Several tools to **bring together key stakeholders** and to foster a health data culture
Health data sharing, a major priority for the European Commission and European health policy

Objective
remove obstacles to the smooth functioning of the data economy

Health data fragmentation
Multiple conditions for data use
Diversity of access governance models

Solutions
create an EU-wide governance framework for data access and use

Data Governance Act
2020

Joint Action TEHDAS “Towards a European Health Data Space”
2021

Pilot version of European Health Data Space: call for proposals financed up to 5m€
2021

European Health Data Space legislative proposal published May 3rd
2022
The Health Data Hub ensures data interoperability

Health data around the world, the need of a common data model for large scale data use

Analytic methods
multiple non interoperable data formats

OMOP-CMP internationally renowned data model

Relational data model centred around a patient table

Standard vocabularies and terminologies allowing interoperability

Opensource program libraries

Omnopisation building interoperable databases
Panel Discussion

1. **Estonia.** Marek Oja, Institute of Computer Science, University of Tartu
2. **Finland.** Javier Gracia-Tabuenca, FinnGen
3. **Denmark.** Andi Tsouchnika, Center for Surgical Science, Zealand University Hospital
4. **Norway.** Eimir Hurley, University of Oslo
5. **Germany.** Michele Zoch, Technische Universität Dresden
6. **Italy.** Lucia Sacchi, University of Pavia
7. **Greece.** Pantelis Natsiavas, Centre for Research & Technology Hellas
8. **Ukraine.** Mariia Kolesnyk, SciForce
9. **Israel.** Guy Livne, Israel Ministry of Health
10. **France.** Lorien Benda, Health Data Hub
Coffee Break