
EUROPEAN OHDSI
SYMPOSIUM
EUROPE
Scaling up reliable evidence
across Europe
June 1 - 3 2024
Rotterdam


OHDSI

Welcome to the European OHDSI Journey

Prof. dr. ir. Peter R. Rijnbeek

Chair Department of Medical Informatics

Erasmus MC, The Netherlands

Thank you for your support!

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Universitair Medisch Centrum Rotterdam

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EUROPE
OHDSI
OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS
Open Science Community
Driving Scalability of Reliable Evidence Generation

Mission and Vision

OHDSI
OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

Our Mission

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

Our Vision

A world in which observational research produces a comprehensive understanding of health and disease.

Why OHDSI Europe?

- Improving interoperability of data in Europe is very much needed and requires expertise in Europe.
- The number of projects in Europe that are building on OMOP is strongly increasing, even within institutions.
- Thera are >200 data sources in Europe mapped to OMOP and we just got started.

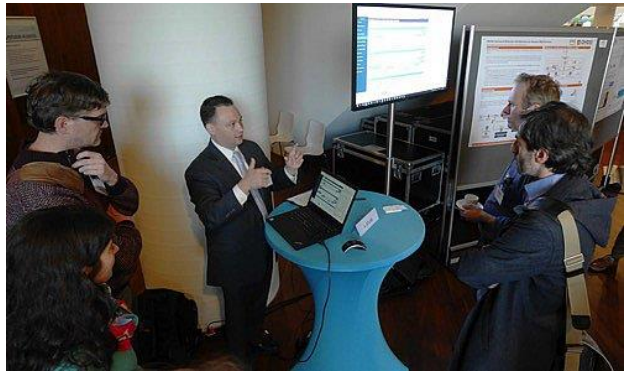
Objectives of OHDSI Europe

- 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
  - Organization of European OHDSI Symposia
  - Training of stakeholders
  - Stimulate national and international collaborations in Europe -> National Nodes.

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

Third Annual OHDSI Symposium, June 24th 2022

- 350 participants
- 80 posters
- 4 software demos
- 2 days with tutorials and workshops

Made by Sarah Seager

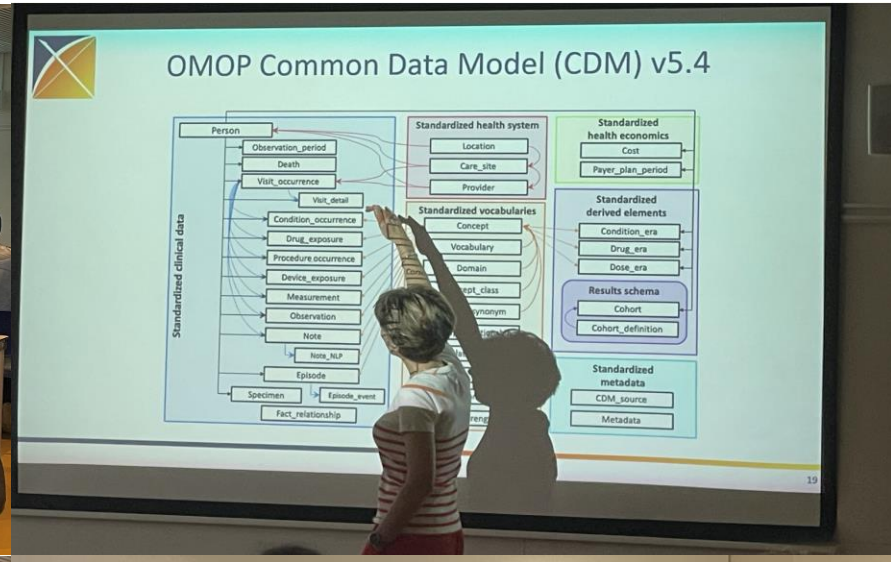
4th Annual OHDSI Symposium, July 3rd 2023

- 350 participants
- 100 posters
- 4 software demos
- 2 days with tutorials and workshops

Meeting Goals Fifth OHDSI Symposium

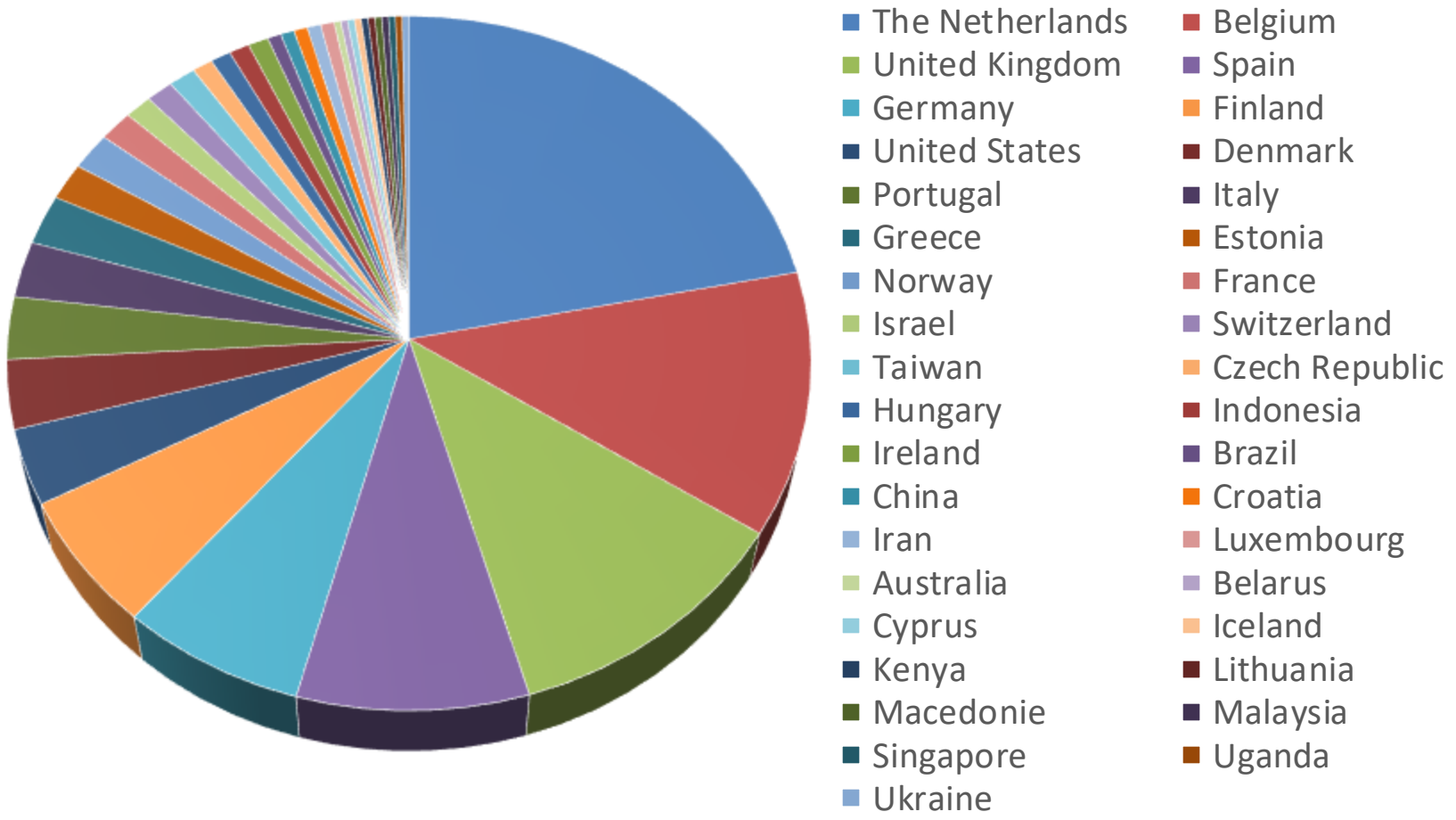
- Educate and train the community through workshop (Saturday) and multiple Workgroup Meetings (Sunday) (200 participants)
- Facilitate meetings for national nodes and its leadership meeting. Data Partner meetings.
- 360 Participants, 130 submissions for collaborator showcase, 13 software demos

Thanks to all faculty !!



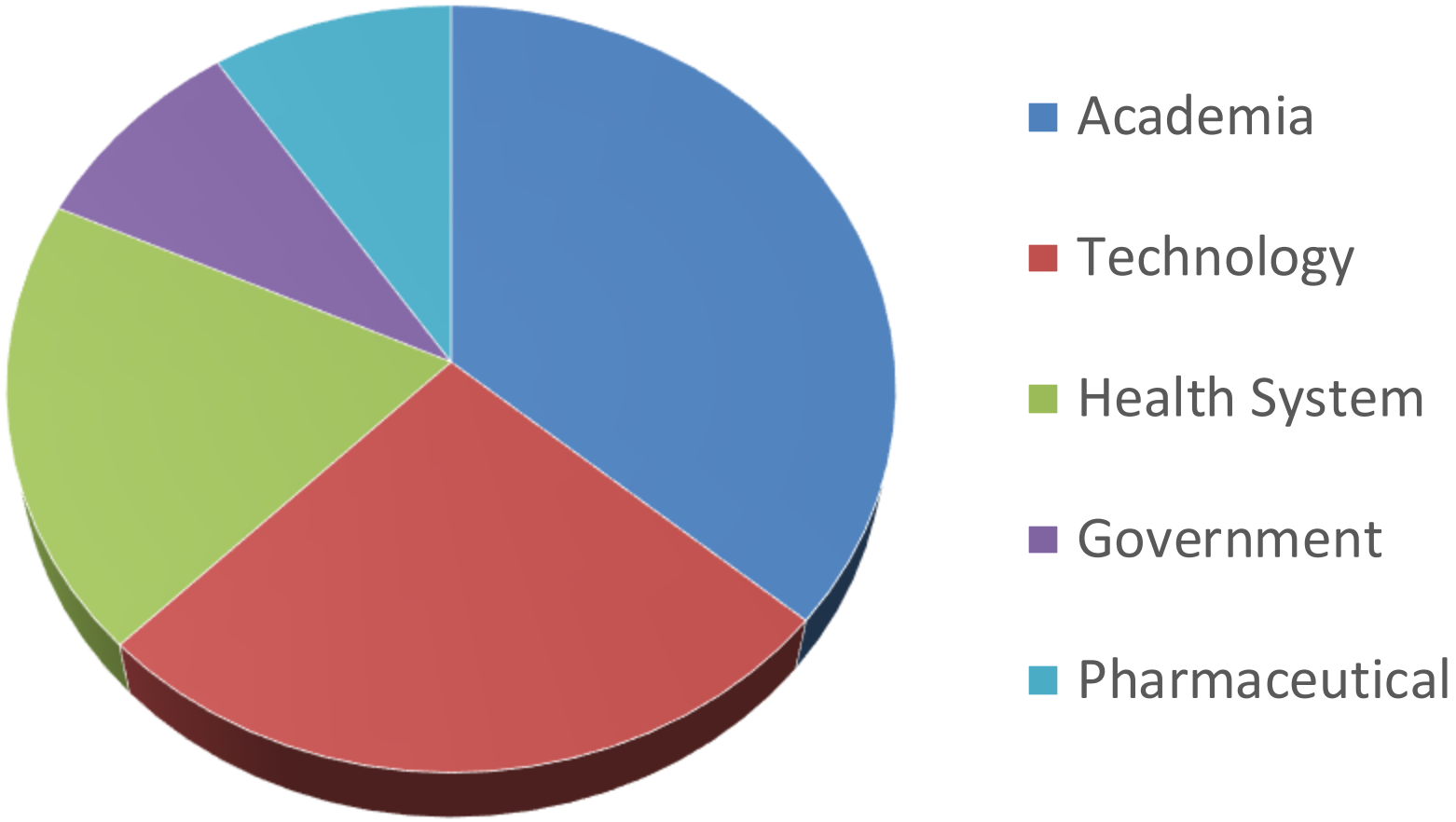
Thanks to all faculty !!

Breakdown of Participants: 37 Countries



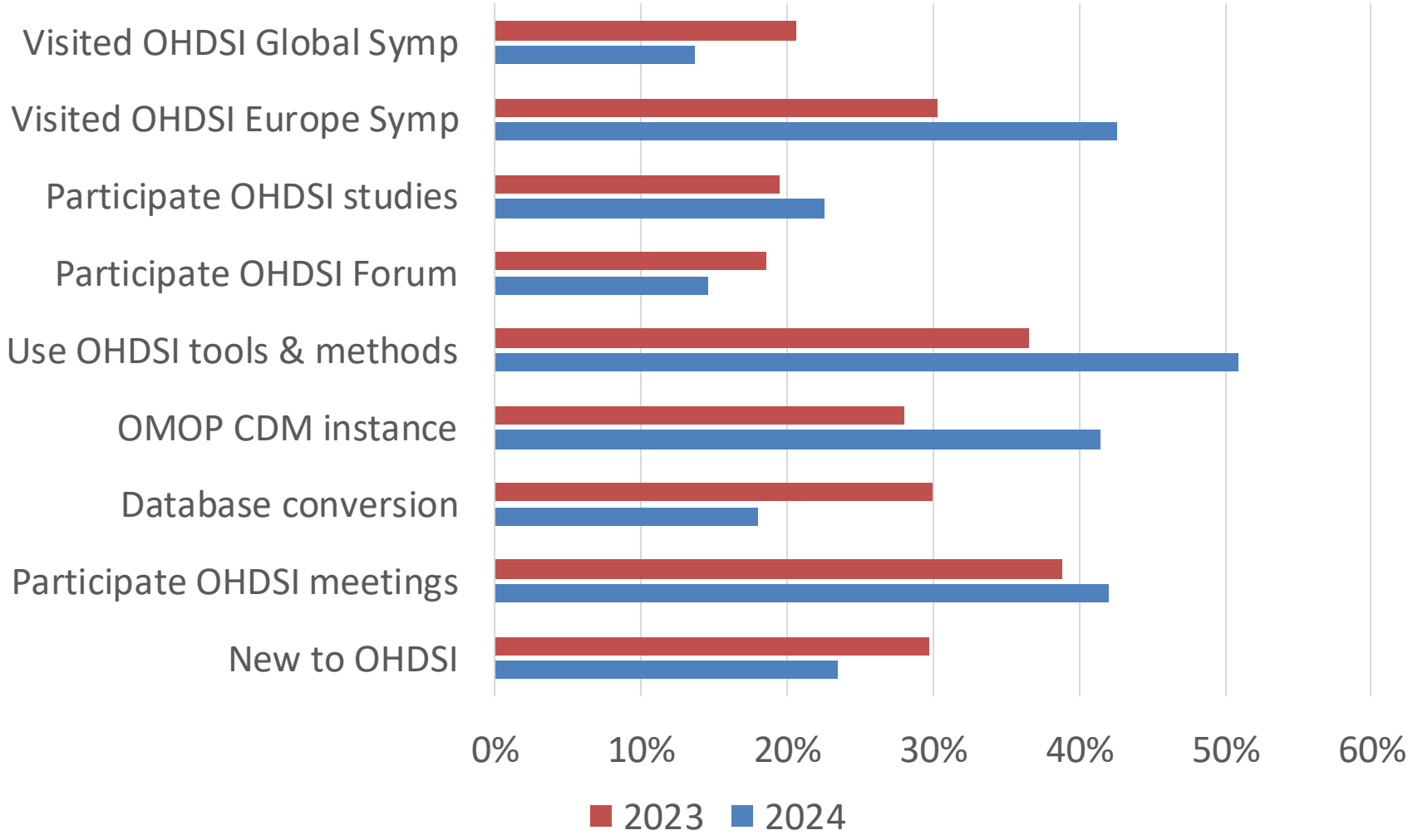
2023: 28 countries

Breakdown of Participants: Stakeholders



2023: same distribution

Relationship with OHDSI



Agenda

Time	Title	Location
9:10 – 9:40	**Journey of OHDSI: Where have we been and where can we go together?** Speaker: Patrick Ryan, PhD, Janssen Research and Development, Department of Biomedical Informatics, Columbia University Medical Center	Theatre
9:40 – 11:00	**Selection of European Initiatives Using the OMOP CDM** Moderator: Renske Los, PhD, Assistant Professor of Medical Informatics, Department of Medical Informatics, Erasmus MC Multiple presentations of European Projects and Initiatives	Theatre
11:00 – 11:30	**Coffee Break**	Queen's Lounge
11:30 – 12:45	**Collaborator Showcase: Rapid fire presentations** Moderator: Katia Verhamme, MD, Associate Professor of Use and Analysis of Observational Data, Department of Medical Informatics, Erasmus MC, Rotterdam.	Theatre
12:45 – 13:45	**Lunch**	La Fontaine & Odyssee Room

Agenda (2)

Time	Title			Location
13:00 – 16:00	**OHDSI Collaborator Showcase** Poster presentations and open-source software demonstrations from OHDSI collaborators: - Observational data standards and management - Open-source analytics development - Clinical applications - Methodological research - National nodes	La Fontaine & Odyssee Room	**Early Investigators Mentor Meetings (14:00 – 15:00)** Lead: Ross Williams, Assistant Professor, Department of Medical Informatics, Erasmus MC Rotterdam	Queen's Lounge
16:00 – 17:10	**Large Scale Evidence Generation in EHDEN and DARWIN EU®** Moderators: Prof. Dani Prieto Alhambra and Katia Verhamme, Associate Professor, Department of Medical Informatics, Erasmus MC			Theatre
17:10 – 17:30	**What evidence are we going to showcase at OHDSI Europe in 2025?** Moderator: Patrick Ryan, Johnson & Johnson, Columbia University			Theatre
17:30 – 18:00	**Closure**			Theatre
18:00 – 19:30	**Networking Reception**			Queen's Lounge

Journey of OHDSI: Where have we been and where can we go together?

Patrick Ryan PhD

Johnson & Johnson

Columbia University Irving Medical Center

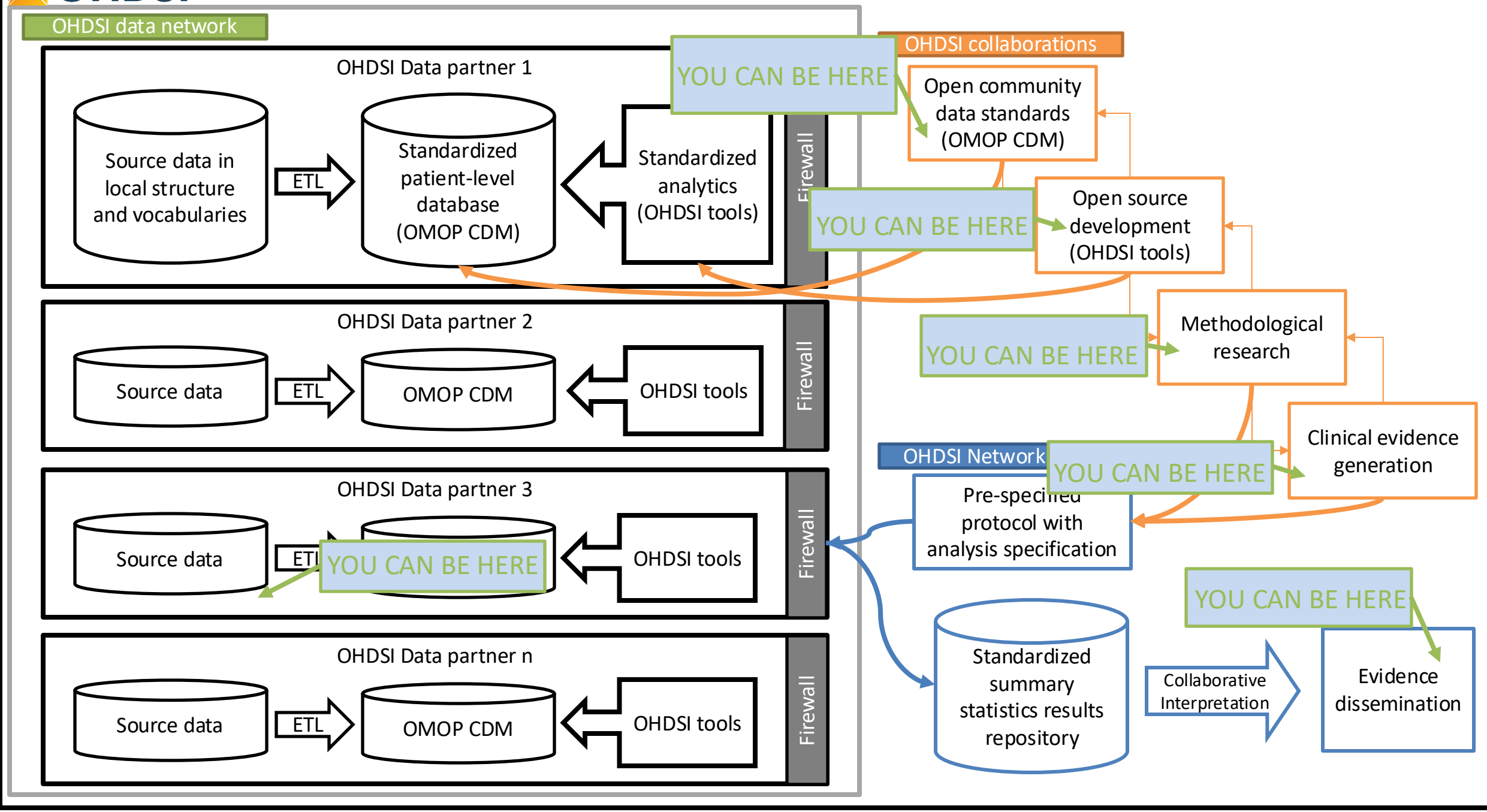
An objective evaluation on how far we've made it on our journey….

OHDSI's mission

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

OHDSI

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



Map of collaborators

OHDSI By The Numbers

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

Regional Chapters and National Nodes

An OHDSI regional chapter represents a group of OHDSI collaborators located in a geographic area who wish to hold local networking events and meetings to address problems specific to their geographic location.

The OHDSI Europe Chapter, in collaboration with the EHDEN project, recently created National Nodes to facilitate national and international collaborations.

An OHDSI Europe National Node is a collection of research institutes within a member country. The Node builds on the strengths of the stakeholders and scientific communities of that country.

Each Node has a lead institute that oversees the work of that Node and assigns a lead and co-lead.

Check out today during the Showcase!

OHDSI in Africa and Partnerships with European Institutions

Other upcoming OHDSI Activities:

- OHDSI India 5Oct2024
- OHDSI Global 22-24Oct2024 (USA)
- OHDSI APAC 6-9Dec2024 (Singapore)

Regional Chapters

Africa
Leads: Ahmed El Sayed, Cynthia Sung

Australia
Lead: Nicole Pratt

China
Lead: Hua Xu

Europe
Lead: Peter Rijnbeek

India
Lead: Lakshmi Kubendran

Japan
Lead: Tatsuo Hiramatsu

Republic of Korea
Lead: Seng Chan You

Singapore
Lead: Mengling 'Mornin' Feng

Taiwan
Lead: Jason Hsu

European National Nodes

Belgium
Lead Institutions: Hasselt University, University Hospital Antwerp

Germany
Lead Institution: Technische Universität Dresden

Greece
Lead Institution: The Institute of Applied Biosciences, Centre for Research and Technology Hellas

Italy
Lead Institution: University of Pavia

Luxembourg
Lead Institutions: Luxembourg Institute of Health, Information Technology for Translational Medicine S.A.

The Netherlands
Lead Institution: Erasmus MC University Medical Center

Portugal
Lead Institution: Centro Hospitalar E Universitario De Coimbra Epe

Spain
Lead Institutions: Consorci Parc de Salut Mar Barcelona, IDIAPJGol

United Kingdon
Lead Institution: Health Data Sciences Section, Botnar Research Centre, University of Oxford

Standby for the next presentation on progress on OHDSI Europe National Nodes

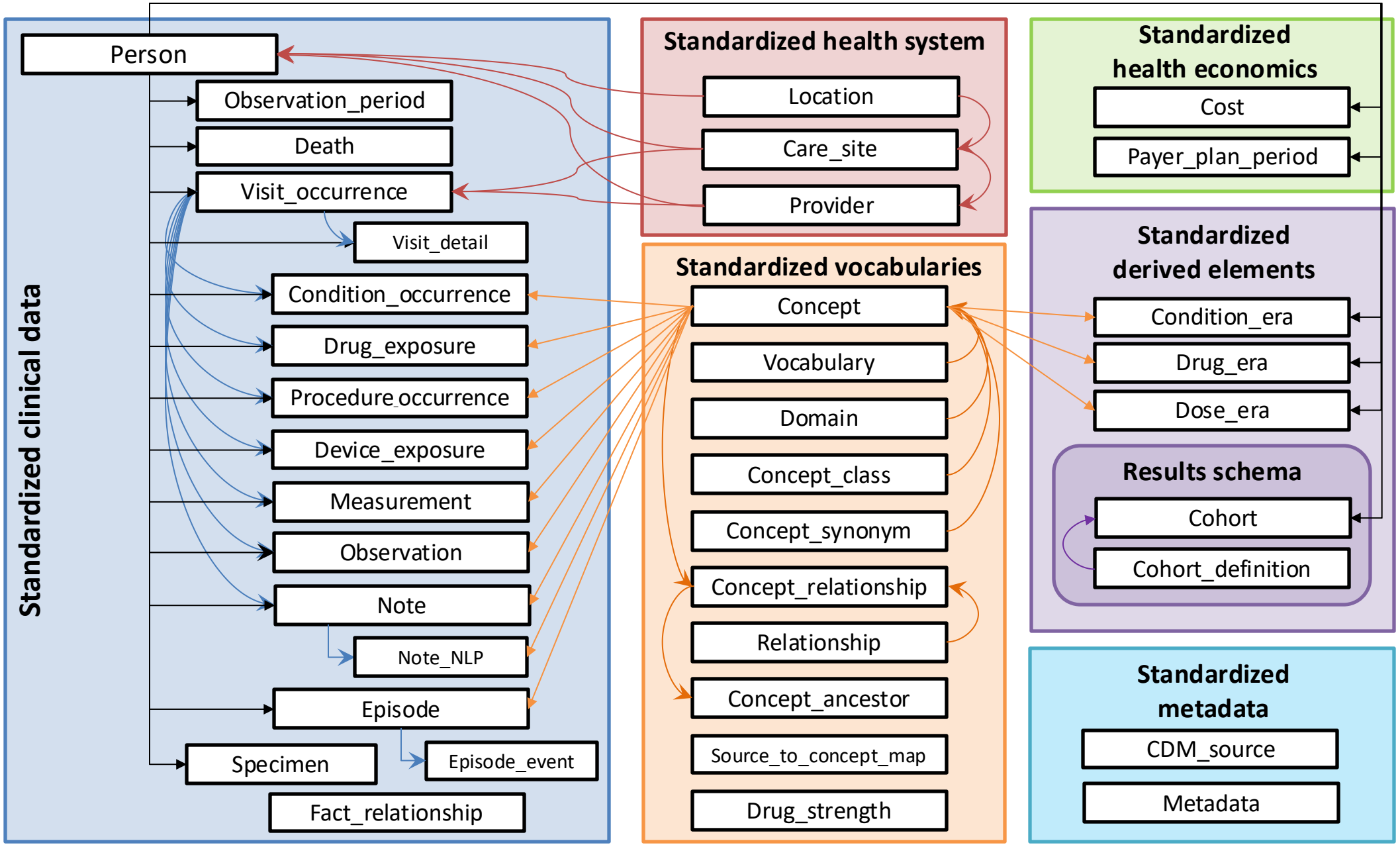
OHDSI Workgroups

OHDSI has a central mission to improve health globally, but there are countless areas where our community can be of service. Work around data, methods, open-source tools, and clinical applications are all pieces of the puzzle, and within OHDSI, there are opportunities to work in any or many of these areas.

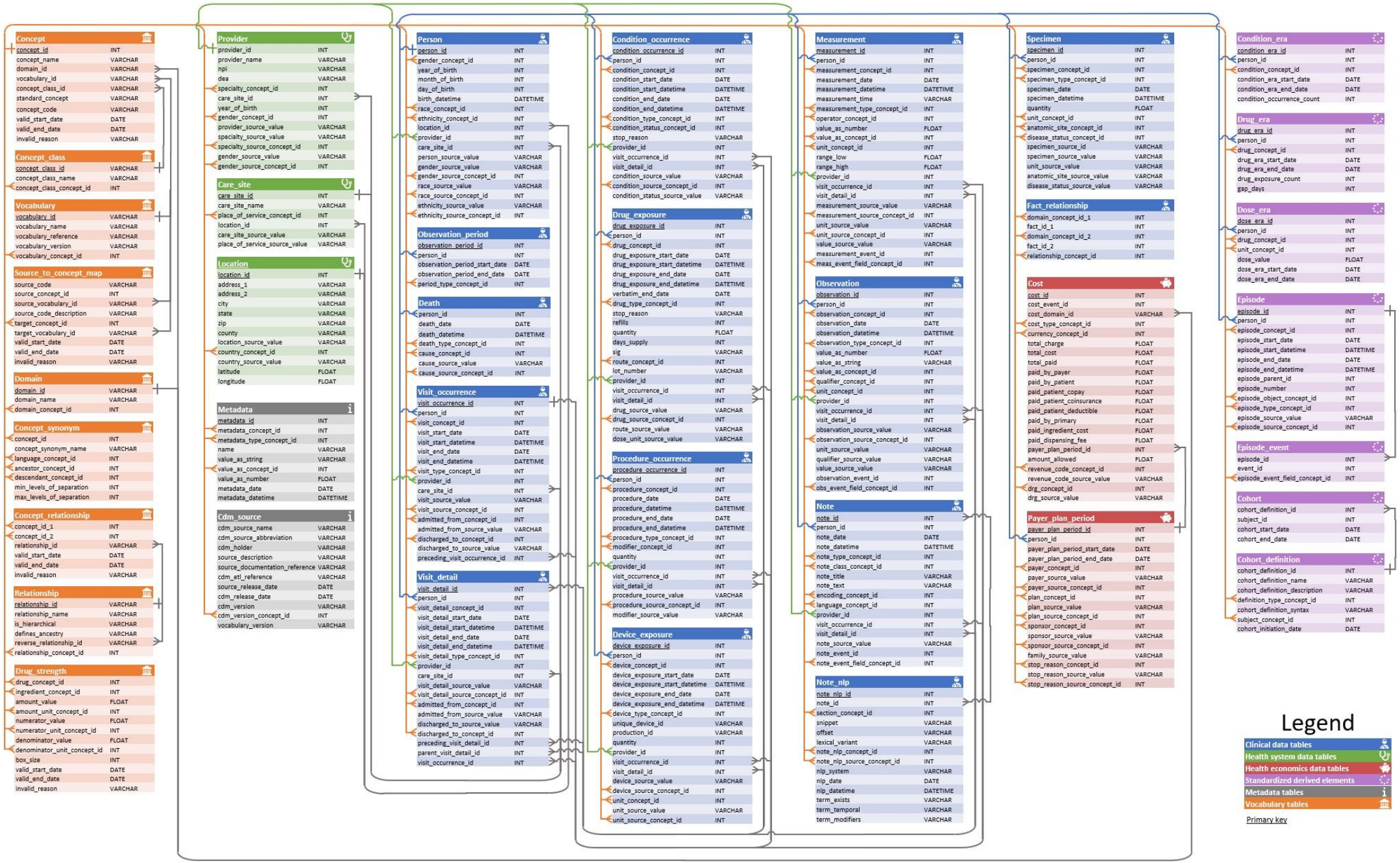
Our workgroups, led by the extraordinary leads shown on these pages, present opportunities for all community members to find a home for their talents and passions, and make meaningful contributions. We are always looking for new collaborators. See an area where you want to contribute? Please Join The Journey!

www.ohdsi.org/workgroups

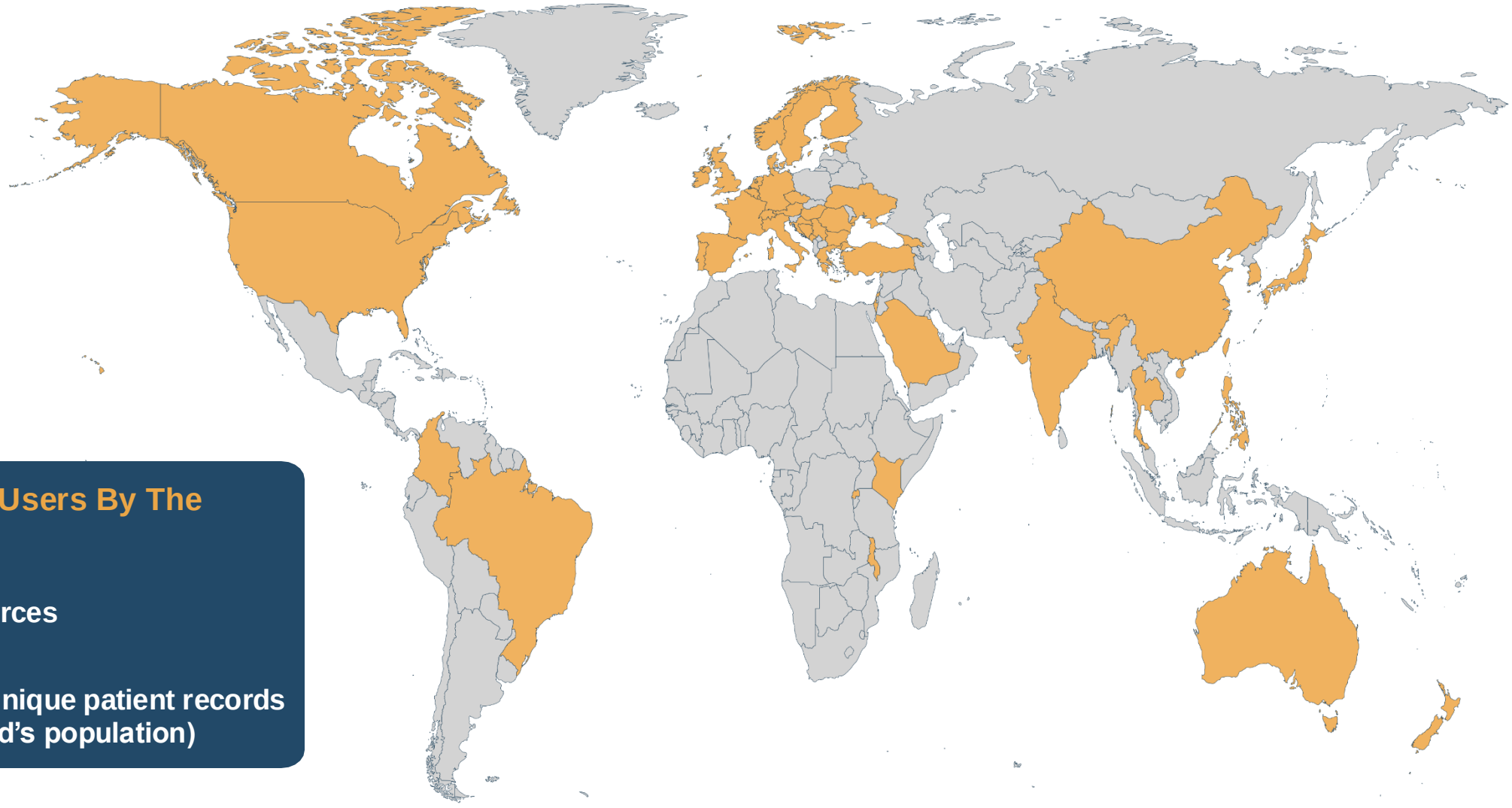
OMOP Common Data Model v5.4



OMOP Common Data Model 5.4



OMOP Common Data Model adoption



OMOP CDM Users By The Numbers

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

OHDSI Evidence Network

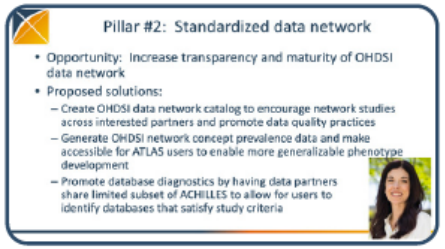
OHDSI is proud to have a global community dedicated to generating real-world evidence and which recognizes the opportunity to collaborate together as part of a distributed network based on standardized data and standardized analytics.

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

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

A message from Common Data Model workgroup lead Clair Blacketer …

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



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

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

Organizations and Data Sources in the OHDSI Evidence Network

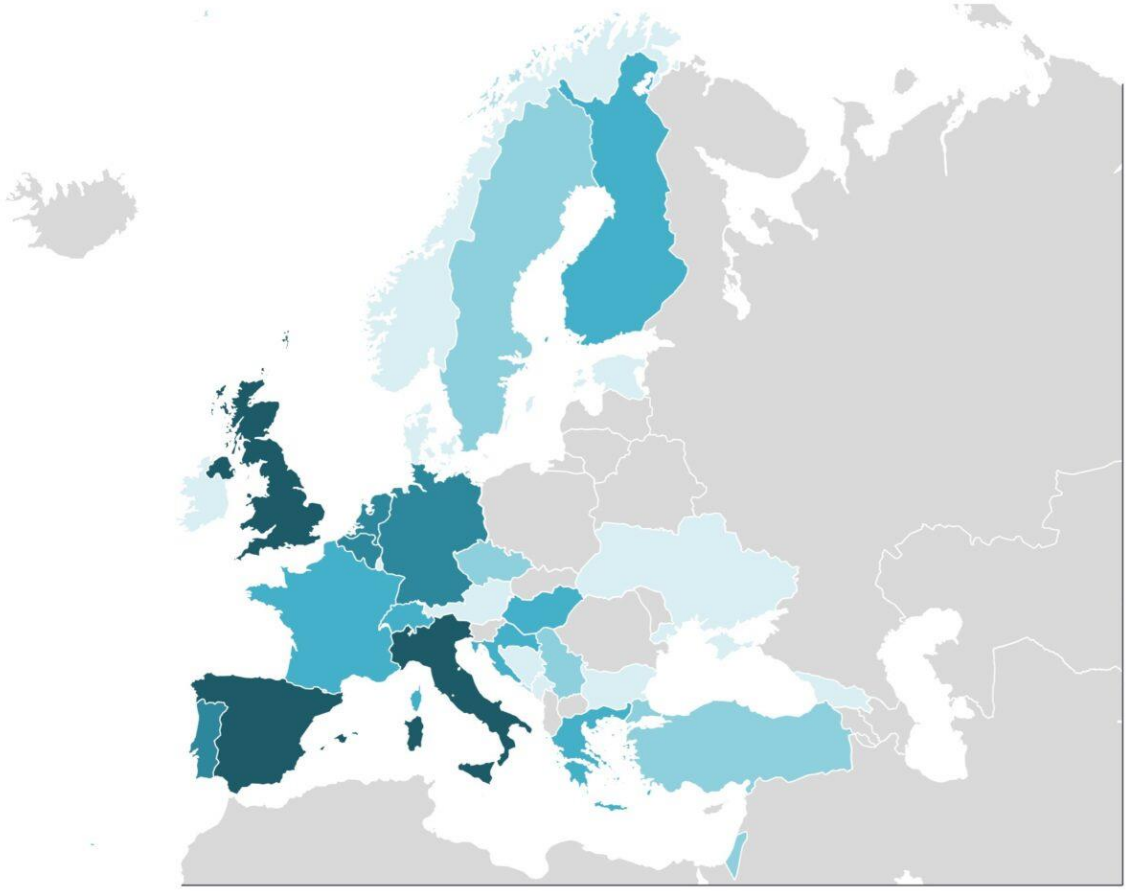
Ajou University • Ajou University
Casa di Cura Igea • Casa di Cura Igea
Clinical Center of Montenegro • Clinical Center of Montenegro
Columbia University Medical Center • Columbia University Medical Center
Hong Kong University • UK THIN
IQVIA • Australia EMR
IQVIA • Disease Analyzer France
IQVIA • Disease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

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

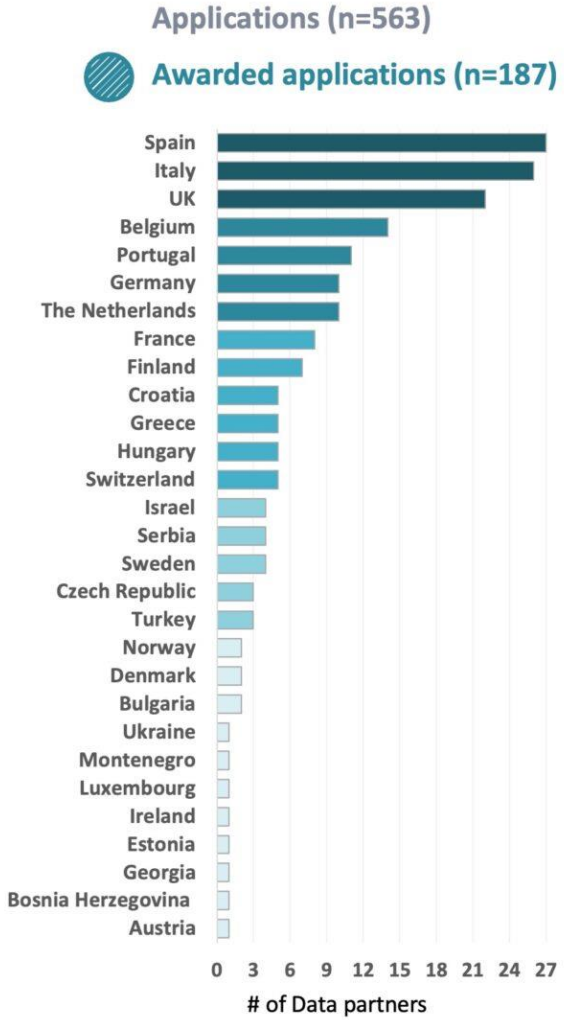
If you are interested in becoming a part of the OHDSI Evidence Network and contributing to advancing evidence-based healthcare, please use the provided QR code to complete a brief form about your organization and your data source. A member of the OHDSI Network Data Quality Working Group will reach out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

Join The OHDSI Evidence Network

EHDEN

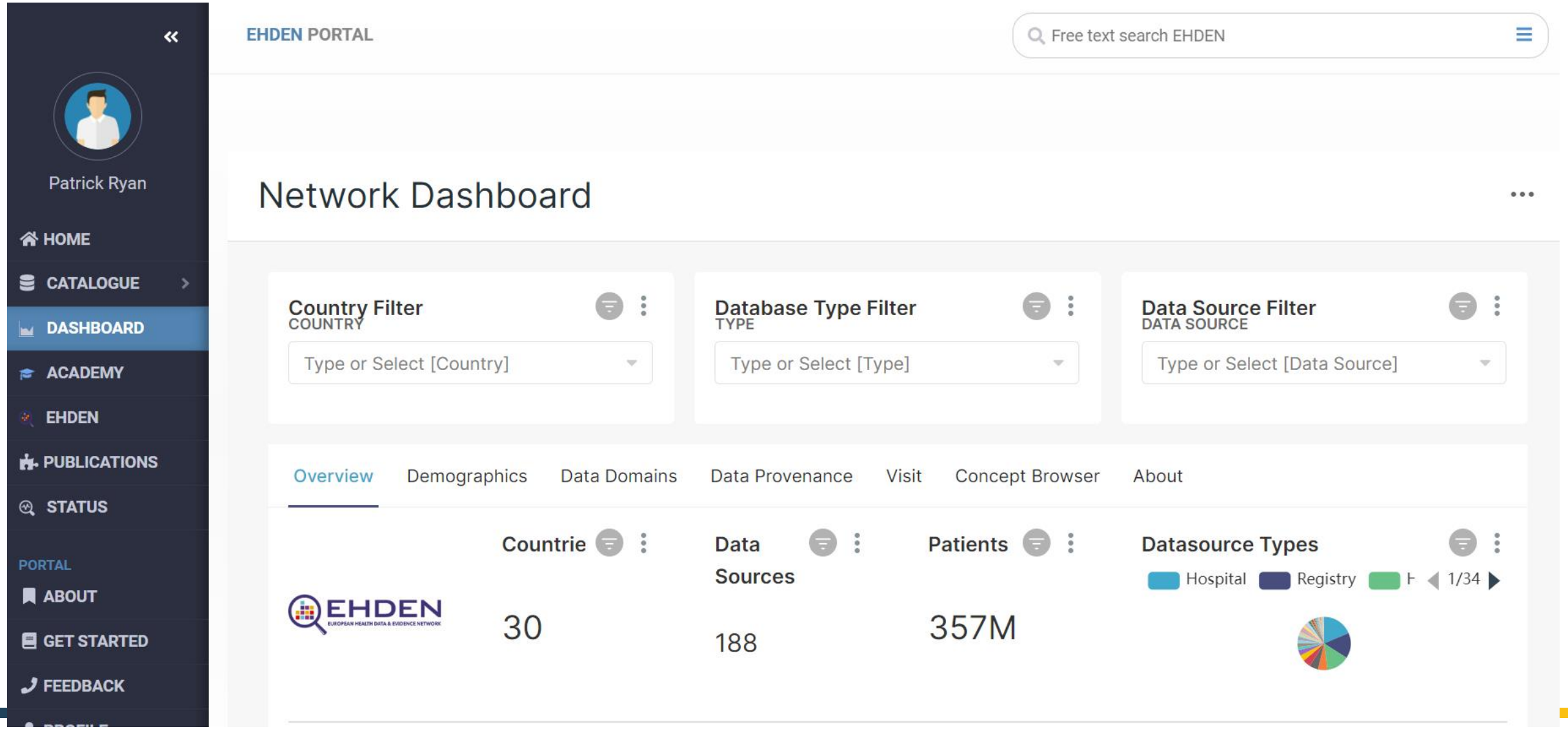


Geographic spread of data partners. The shade of blue indicates the # of data partners in that country (darker = more)



187 Data Partners from 29 different countries = >33% of OMOP CDM adopters and >59% of countries

EHDEN portal



Due to a new release taking place on 3rd June between 08:00-09:00 CET, users should refrain from submitting or editing records during this time as an

HMA-EMA

The Catalogues for r

Page content

Common Data Model (CDM) mapping

CDM mapping Has the data source been converted (ETL-ed) to a common data model?	Yes

CDM Mappings

CDM name	OMOP
CDM website	https://www.ohdsi.org/Data-standardization/
Data source ETL frequency	6,00 months
Data source ETL status	Completed

EHDEN is advancing the science of data networks

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Research and Applications

AMIA OXFORD

Research and Applications

European Health Data & Evidence Network—learnings from building out a standardized international health data network

Erica A. Voss, MPH*[,1,2,3], Clair Blacketer, MPH[1,2,3], Sebastiaan van Sandijk, MSc[1,4], Maxim Moinat, MSc[1,2], Michael Kallfelz, MD[1,4], Michel van Speybroeck, MSc[3], Daniel Prieto-Alhambra, PhD[1,2,5], Martijn J. Schuemie, PhD[1,3,6], Peter R. Rijnbeek, PhD[1,2]

[1]OHDSI Collaborators, Observational Health Data Sciences and Informatics (OHDSI), New York, NY, United States, [2]Department of Medical Informatics, Erasmus University Medical Center, Rotterdam, the Netherlands, [3]Janssen Pharmaceutical Research and Development LLC, Raritan, NJ 08869, United States, [4]Odysseus Data Services, Prague, Czech Republic, [5]Centre for Statistics in Medicine, NDORMS, University of Oxford, Oxford, United Kingdom, [6]Department of Biostatistics, University of California, Los Angeles, CA 90095, United States

*Corresponding author: Erica A. Voss, MPH, Janssen Research & Development – Epidemiology, 920 US Highway 202, Raritan, NJ 08869 (evoss3@its.jnj.com)

Abstract

Objective: Health data standardized to a common data model (CDM) simplifies and facilitates research. This study examines the factors that make standardizing observational health data to the Observational Medical Outcomes Partnership (OMOP) CDM successful.

Materials and methods: Twenty-five data partners (DPs) from 11 countries received funding from the European Health Data Evidence Network (EHDEN) to standardize their data. Three surveys, DataQualityDashboard results, and statistics from the conversion process were analyzed qualitatively and quantitatively. Our measures of success were the total number of days to transform source data into the OMOP CDM and participation in network research.

Results: The health data converted to CDM represented more than 133 million patients. 100%, 88%, and 84% of DPs took Surveys 1, 2, and 3. The median duration of the 6 key extract, transform, and load (ETL) processes ranged from 4 to 115 days. Of the 25 DPs, 21 DPs were considered applicable for analysis of which 52% standardized their data on time, and 48% participated in an international collaborative study.

Discussion: This study shows that the consistent workflow used by EHDEN proves appropriate to support the successful standardization of observational data across Europe. Over the 25 successful transformations, we confirmed that getting the right people for the ETL is critical and vocabulary mapping requires specific expertise and support of tools. Additionally, we learned that teams that proactively prepared for data governance issues were able to avoid considerable delays improving their ability to finish on time.

Conclusion: This study provides guidance for future DPs to standardize to the OMOP CDM and participate in distributed networks. We demonstrate that the Observational Health Data Sciences and Informatics community must continue to evaluate and provide guidance and support for what ultimately develops the backbone of how community members generate evidence.

Key words: OMOP common data model; observational data; data standardization.

Check out today during the Showcase!

CDMOnboarding R package for data quality assessment

Lessons learned from EHDEN Data Partner Reviews: Improving ETL Processes and Data Quality in OMOP CDM Conversions

OHDSI Vocabularies Improvement Initiative

Landscape assessment

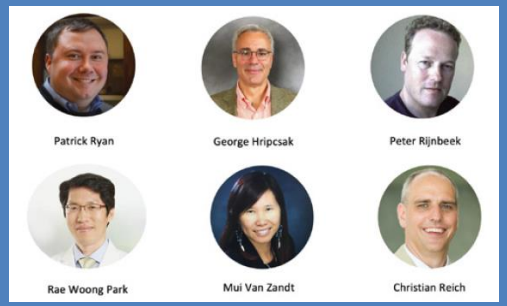
FINDINGS

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

NEEDS

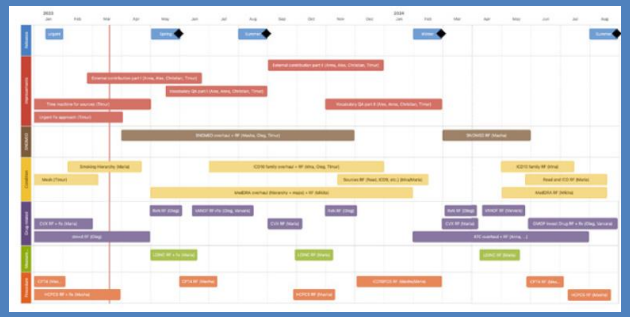
- Transparent release schedule
- Vocabulary changes, versioning
- Transparent QA/QC
- Better coverage and hierarchies
- More documentation and educational materials

Vocabulary committee

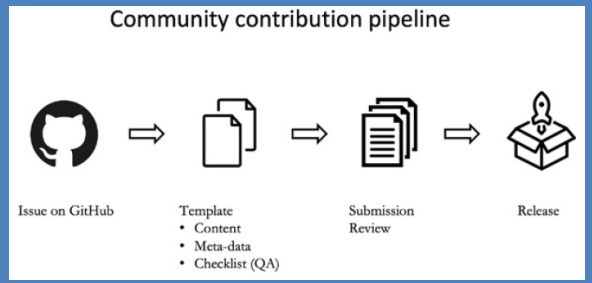


Vocabulary team

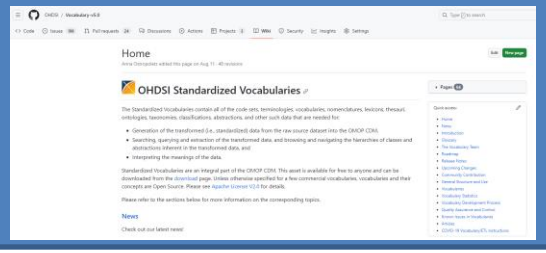
Release schedule and roadmap



Community contributions



Quality framework & documentation



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Advance access publication 4 January 2024
Research and Applications

Research and Applications

OHDSI Standardized Vocabularies—a large-scale centralized reference ontology for international data harmonization

Christian Reich, MD[1,2,3,*], Anna Ostropolets, PhD[1,4,5], Patrick Ryan, PhD[1,4,6], Peter Rijnbeek, PhD[1,3], Martijn Schuemie, PhD[1,6], Alexander Davydov, MD[1,5], Dmitry Dymshyts, MD[1,6], George Hripcsak, MD[1,4]

[1]Coordinating Center, Observational Health Data Sciences and Informatics, New York City NY 10032, United States, [2]OHDSI Center at the Roux Institute, Northeastern University, Portland ME 04101, United States, [3]Department of Medical Informatics, Erasmus University Medical Center, 3015 GD Rotterdam, The Netherlands, [4]Department of Biomedical Informatics, Columbia University Medical Center, New York City NY 10032, United States, [5]Odysseus Data Services, Cambridge MA 02142, United States, [6]Observational Health Data Analytics, Janssen Research & Development, Titusville NJ 08560, United States

*Corresponding author: Christian Reich, MD, OHDSI Center at the Roux Institute, Northeastern University, 100 Fore St, Portland ME 04101 (reich@ohdsi.org)

Abstract

Importance: The Observational Health Data Sciences and Informatics (OHDSI) is the largest distributed data network in the world encompassing more than 331 data sources with 2.1 billion patient records across 34 countries. It enables large-scale observational research through standardizing the data into a common data model (CDM) (Observational Medical Outcomes Partnership [OMOP] CDM) and requires a comprehensive, efficient, and reliable ontology system to support data harmonization.

Materials and methods: We created the OHDSI Standardized Vocabularies—a common reference ontology mandatory to all data sites in the network. It comprises imported and *de novo*-generated ontologies containing concepts and relationships between them, and the praxis of converting the source data to the OMOP CDM based on these. It enables harmonization through assigned domains according to clinical categories, comprehensive coverage of entities within each domain, support for commonly used international coding schemes, and standardization of semantically equivalent concepts.

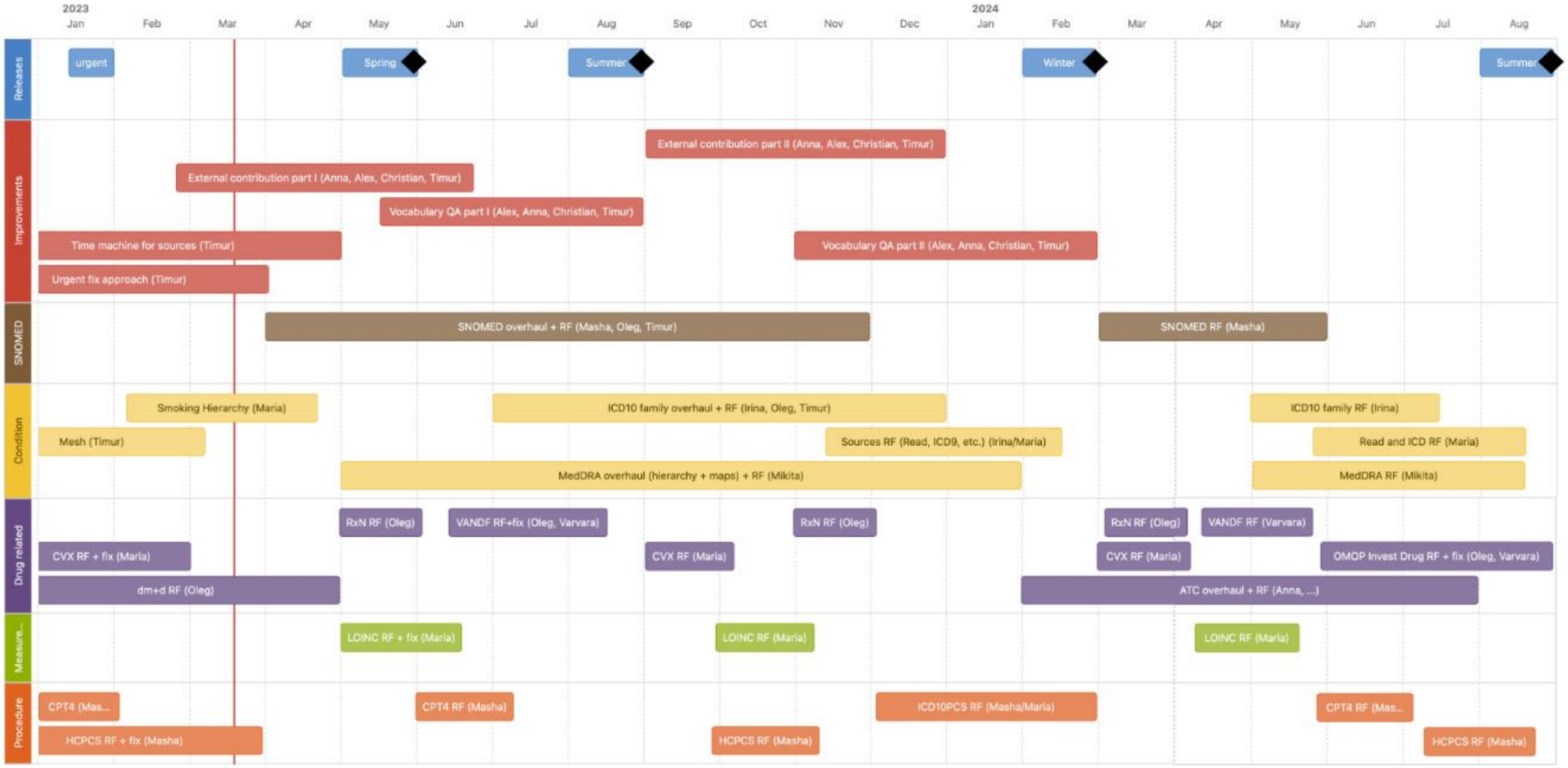
Results: The OHDSI Standardized Vocabularies comprise over 10 million concepts from 136 vocabularies. They are used by hundreds of groups and several large data networks. More than 8600 users have performed 50 000 downloads of the system. This open-source resource has proven to address an impediment of large-scale observational research—the dependence on the context of source data representation. With that, it has enabled efficient phenotyping, covariate construction, patient-level prediction, population-level estimation, and standard reporting.

Discussion and conclusion: OHDSI has made available a comprehensive, open vocabulary system that is unmatched in its ability to support global observational research. We encourage researchers to exploit it and contribute their use cases to this dynamic resource.

Key words: OHDSI; controlled vocabulary; common data model; observational data.

OHDSI Standardized Vocabularies roadmap

Roadmap 2023 Q1 - 2024 Q2:



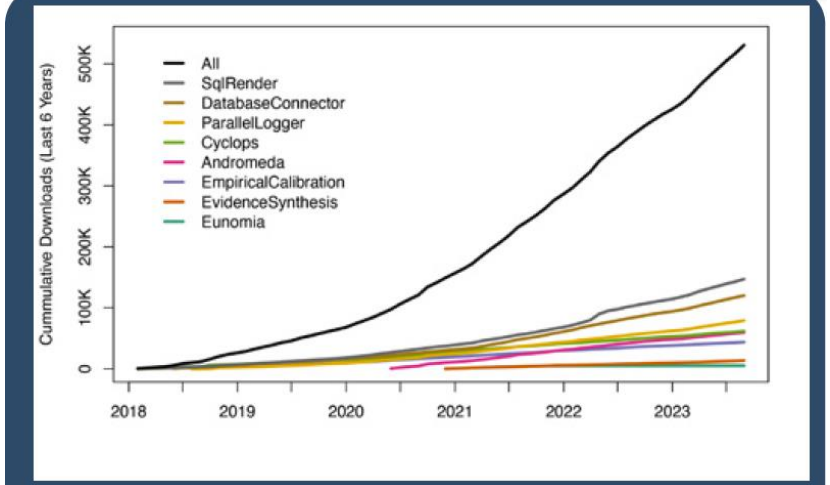
HADES

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

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

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

Learn more about the individual HADES packages in this section.



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

HADES Maintainers

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

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

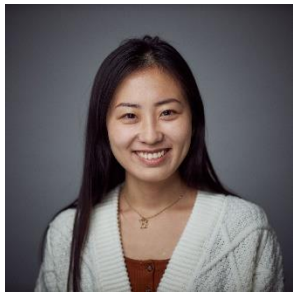
Shout out to the DARWIN-EU Development team!



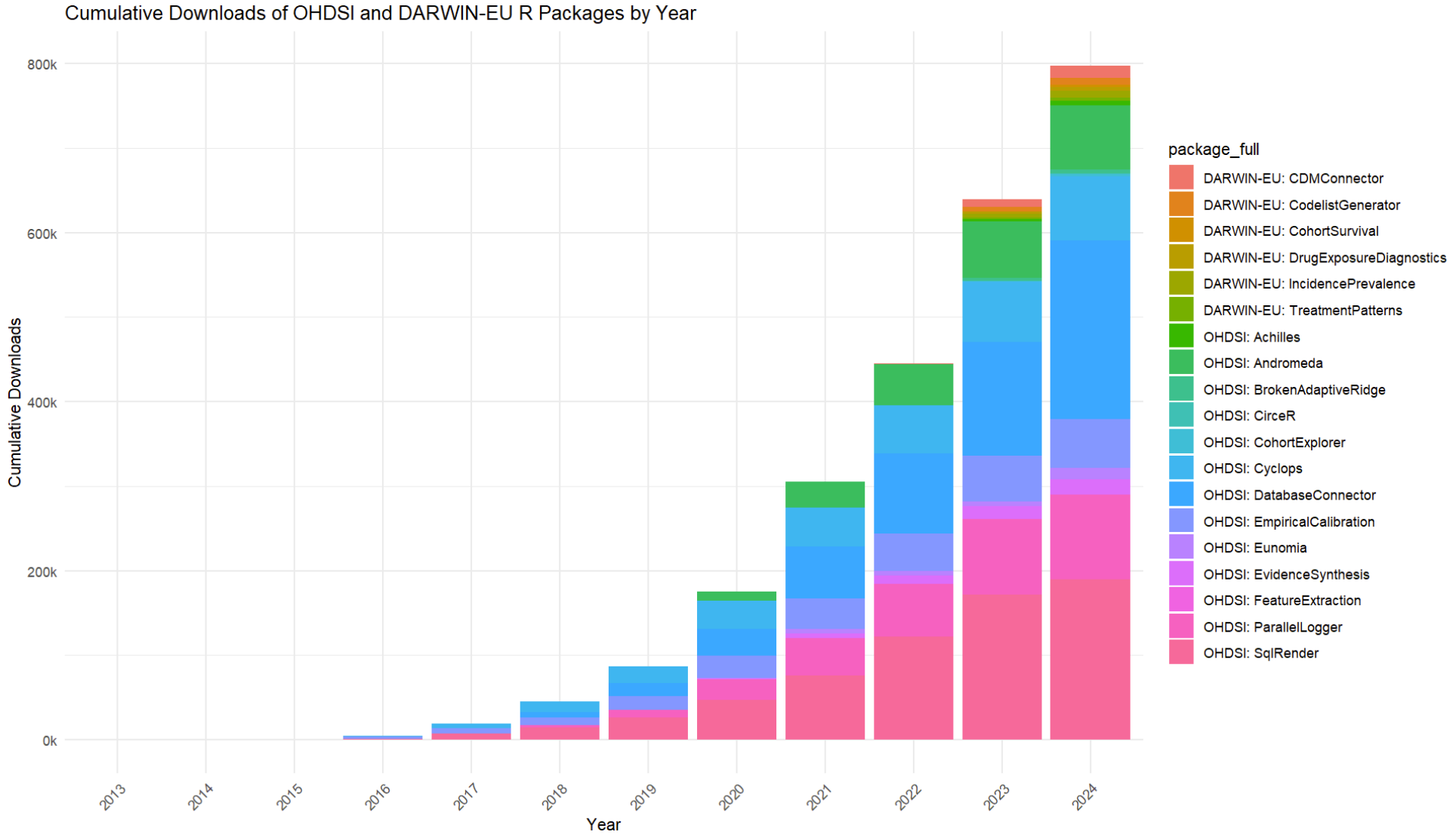




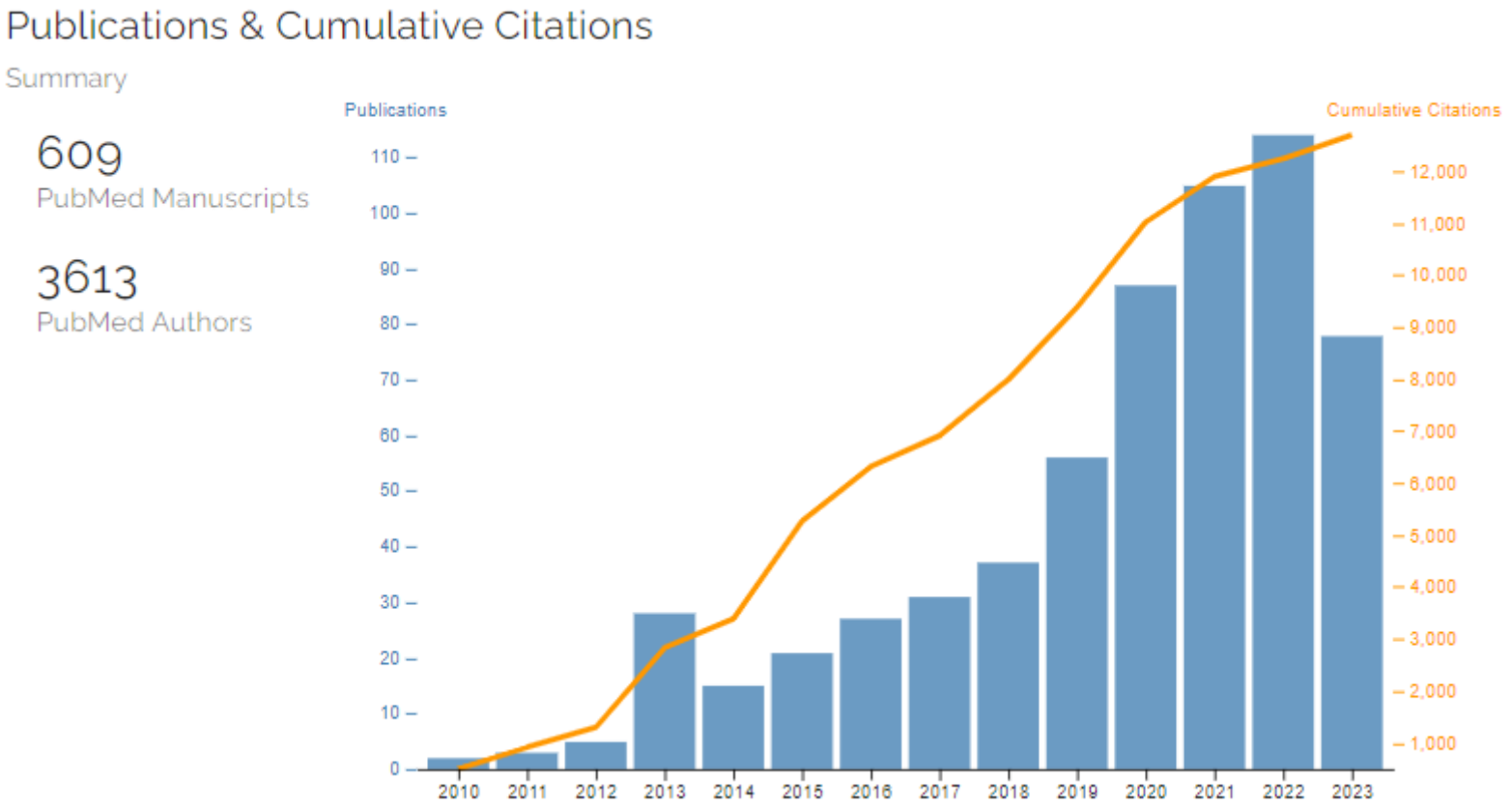




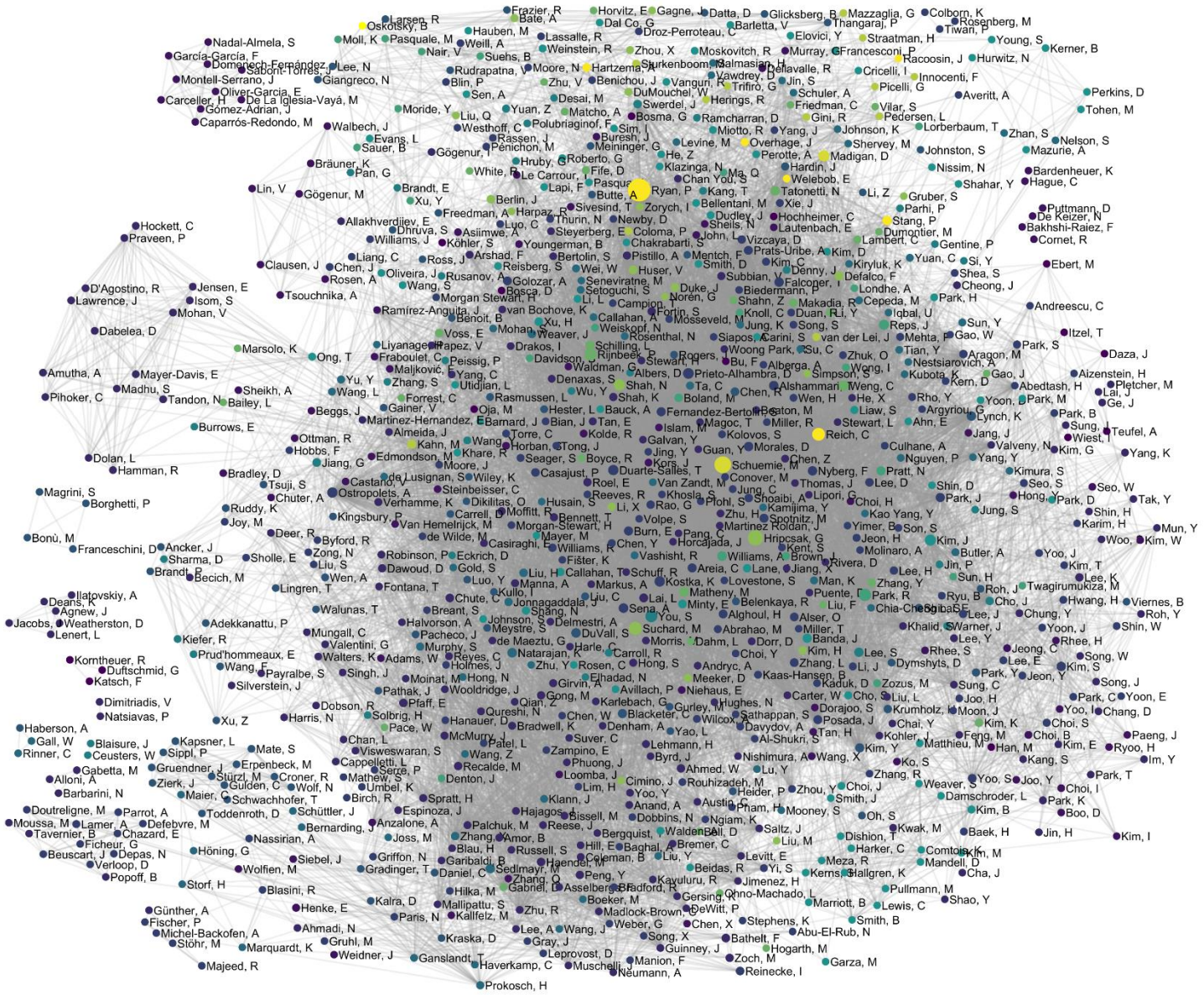

Open-source development accessible on R CRAN



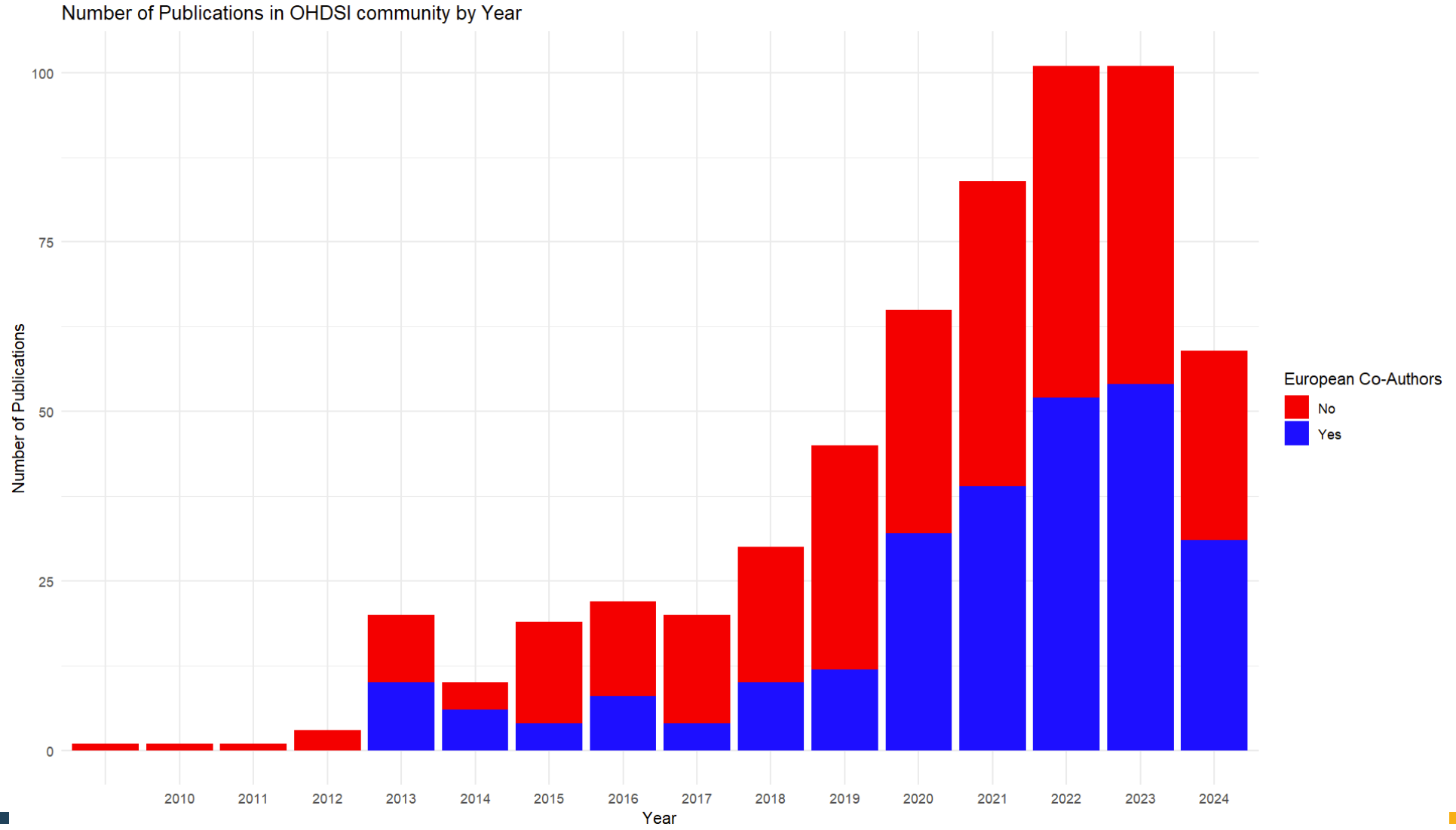
OHDSI scholarship



OHDSI collaborations in scholarship



OHDSI Europe is growing its impact in community scholarship



OHDSI Europe leading in data standardization

Received: 31 January 2024 | Revised: 19 April 2024 | Accepted: 22 April 2024
DOI: 10.1002/pds.5809

ORIGINAL ARTICLE

PDS Pharmacoepidemiology & Drug Safety

WILEY

Calculating daily dose in the Observational Medical Outcomes Partnership Common Data Model

Theresa Burkard[1] | Kim López-Güell[1] | Artem Gorbachev[2] | Lucía Bellas[3] | Annika M. Jödicke[1] | Edward Burn[1] | Maria de Ridder[4] | Mees Mosseveld[4] | Jasmine Gratton[5] | Sarah Seager[5] | Dina Vojinovic[6] | Miguel Angel Mayer[7,8] | Juan Manuel Ramírez-Anguita[8,9] | Angela Leis Machín[8] | Marek Oja[10] | Raivo Kolde[10] | Klaus Bonadt[11] | Daniel Prieto-Alhambra[1,4] | Chistian Reich[2] | Martí Català[1]

[1]Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford, Oxford, UK
[2]Odysseus Data Services, Cambridge, Massachusetts, USA
[3]Clinical Pharmacology Service, Hospital Universitari Vall d'Hebron, Barcelona, Spain
[4]Department of Medical Informatics, Erasmus University Medical Center, Rotterdam, The Netherlands
[5]IQVIA Ltd, London, UK
[6]IQVIA Solutions B.V, Amsterdam, the Netherlands
[7]Management and Control Department, Hospital del Mar Barcelona, Barcelona, Spain
[8]Research Program on Biomedical Informatics (GRIB). Hospital del Mar Research Institute (IMIM), Barcelona, Spain
[9]Universitat Pompeu Fabra, Barcelona, Spain
[10]Institute of Computer Science, University of Tartu, Tartu, Estonia
[11]IQVIA Commercial GmbH & Co. OHG, Frankfurt, Germany

Correspondence
Daniel Prieto-Alhambra, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford, Windmill Road, OX37LD, Oxford, UK.
Email: daniel.prietoalhambra@ndorms.ox.ac.uk

Funding information
Darwin EU, Grant/Award Number: EMA/2021/08/TDA; EHDEN

Abstract

Purpose: We aimed to develop a standardized method to calculate daily dose (i.e., the amount of drug a patient was exposed to per day) of any drug on a global scale using only drug information of typical observational data in the Observational Medical Outcomes Partnership Common Data Model (OMOP CDM) and a single reference table from Observational Health Data Sciences And Informatics (OHDSI).

Materials and Methods: The OMOP DRUG_STRENGTH reference table contains

OHDSI Europe leading in open-source development

Journal of the American Medical Informatics Association, 2024, **31(5)**, 1093–1101
https://doi.org/10.1093/jamia/ocae044
Advance access publication 12 March 2024
Research and Applications

Research and Applications

Markov modeling for cost-effectiveness using federated health data network

Markus Haug, MSc[1,*], Marek Oja, PhD[1], Maarja Pajusalu, MSc[1], Kerli Mooses, PhD[1], Sulev Reisberg, PhD[1], Jaak Vilo, PhD[1], Antonio Fernández Giménez[2], Thomas Falconer, MSc[3], Ana Danilović, MD[4], Filip Maljkovic, MSc[5], Dalia Dawoud, PhD[6], Raivo Kolde, PhD[1]

[1]Institute of Computer Science, University of Tartu, Tartu 51009, Estonia, [2]Biomedical Research Institute, IIS INCLIVA, Valencia 46010, Spain, [3]Columbia University Irving Medical Center, New York, NY 10032, United States, [4]KBC Zvezdara, Belgrade 11000, Serbia, [5]Department of Health Information Systems, Heliant, Belgrade 11000, Serbia, [6]National Institute for Health and Care Excellence, London WC1V 6NA, United Kingdom

*Corresponding author: Markus Haug, MSc, Institute of Computer Science, University of Tartu, Narva mnt 18, 51009 Tartu, Estonia (markus.haug@ut.ee)

Abstract

Objective: To introduce 2 R-packages that facilitate conducting health economics research on OMOP-based data networks, aiming to standardize and improve the reproducibility, transparency, and transferability of health economic models.

Materials and Methods: We developed the software tools and demonstrated their utility by replicating a UK-based heart failure data analysis across 5 different international databases from Estonia, Spain, Serbia, and the United States.

Results: We examined treatment trajectories of 47 163 patients. The overall incremental cost-effectiveness ratio (ICER) for telemonitoring relative to standard of care was 57 472 €/QALY. Country-specific ICERs were 60 312 €/QALY in Estonia, 58 096 €/QALY in Spain, 40 372 €/QALY in Serbia, and 90 893 €/QALY in the US, which surpassed the established willingness-to-pay thresholds.

Discussion: Currently, the cost-effectiveness analysis lacks standard tools, is performed in ad-hoc manner, and relies heavily on published information that might not be specific for local circumstances. Published results often exhibit a narrow focus, central to a single site, and provide only partial decision criteria, limiting their generalizability and comprehensive utility.

Conclusion: We created 2 R-packages to pioneer cost-effectiveness analysis in OMOP CDM data networks. The first manages state definitions and database interaction, while the second focuses on Markov model learning and profile synthesis. We demonstrated their utility in a multisite heart failure study, comparing telemonitoring and standard care, finding telemonitoring not cost-effective.

Key words: treatment trajectories; cost-effectiveness; Markov chains; observational data; OHDSI CDM.

OHDSI Europe leading in methodological research

Journal of the American Medical Informatics Association, 2024, 1–8
https://doi.org/10.1093/jamia/ocae109
Research and Applications

Research and Applications

Comparing penalization methods for linear models on large observational health data

Egill A. Fridgeirsson, PhD*[,1], Ross Williams, PhD[1], Peter Rijnbeek, PhD[1], Marc A. Suchard, MD, PhD[2,3], Jenna M. Reps, PhD[1,4]

[1]Department of Medical Informatics, Erasmus University Medical Center, 3015 GD Rotterdam, The Netherlands, [2]Department of Biostatistics, University of California, Los Angeles, Los Angeles, CA 90095-1772, United States, [3]VA Informatics and Computing Infrastructure, United States Department of Veterans Affairs, Salt Lake City, UT 84148, United States, [4]Observational Health Data Analytics, Janssen Research and Development, Titusville, NJ 08560, United States

*Corresponding author: Egill A. Fridgeirsson, PhD, Department of Medical Informatics, Erasmus University Medical Center, Dr Molewaterplein 40, 3015 GD Rotterdam, The Netherlands (e.fridgeirsson@erasmusmc.nl)

Abstract

Objective: This study evaluates regularization variants in logistic regression (L1, L2, ElasticNet, Adaptive L1, Adaptive ElasticNet, Broken adaptive ridge [BAR], and Iterative hard thresholding [IHT]) for discrimination and calibration performance, focusing on both internal and external validation.

Materials and Methods: We use data from 5 US claims and electronic health record databases and develop models for various outcomes in a major depressive disorder patient population. We externally validate all models in the other databases. We use a train-test split of 75%/25% and evaluate performance with discrimination and calibration. Statistical analysis for difference in performance uses Friedman's test and critical difference diagrams.

Results: Of the 840 models we develop, L1 and ElasticNet emerge as superior in both internal and external discrimination, with a notable AUC difference. BAR and IHT show the best internal calibration, without a clear external calibration leader. ElasticNet typically has larger model sizes than L1. Methods like IHT and BAR, while slightly less discriminative, significantly reduce model complexity.

Conclusion: L1 and ElasticNet offer the best discriminative performance in logistic regression for healthcare predictions, maintaining robustness across validations. For simpler, more interpretable models, L0-based methods (IHT and BAR) are advantageous, providing greater parsimony and calibration with fewer features. This study aids in selecting suitable regularization techniques for healthcare prediction models, balancing performance, complexity, and interpretability.

Key words: logistic regression; electronic health records; regularization; discrimination; calibration.

OHDSI Europe leading in clinical applications

THE LANCET
Respiratory Medicine

Articles

The effectiveness of COVID-19 vaccines to prevent long COVID symptoms: staggered cohort study of data from the UK, Spain, and Estonia

Martí Català, Núria Mercadé-Besora, Raivo Kolde, Nhung T H Trinh, Elena Roel, Edward Burn, Trishna Rathod-Mistry, Kristin Kostka, Wai Yi Man, Antonella Delmestri, Hedvig M E Nordeng, Anneli Uusküla, Talita Duarte-Salles, Daniel Prieto-Alhambra, Annika M Jödicke**

Summary

Background Although vaccines have proved effective to prevent severe COVID-19, their effect on preventing long-term symptoms is not yet fully understood. We aimed to evaluate the overall effect of vaccination to prevent long COVID symptoms and assess comparative effectiveness of the most used vaccines (ChAdOx1 and BNT162b2).

Methods We conducted a staggered cohort study using primary care records from the UK (Clinical Practice Research Datalink [CPRD] GOLD and AURUM), Catalonia, Spain (Information System for Research in Primary Care [SIDIAP]), and national health insurance claims from Estonia (CORIVA database). All adults who were registered for at least 180 days as of Jan 4, 2021 (the UK), Feb 20, 2021 (Spain), and Jan 28, 2021 (Estonia) comprised the source population. Va… a time-varying exposure, staggered by vaccine rollout period. Vaccinated people were

Lancet Respir Med 2024; 12: 225–36

Published Online January 11, 2024 https://doi.org/10.1016/S2213-2600(23)00414-9

*Joint senior authors

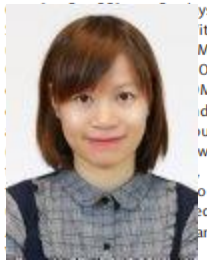
Pharmaco- and Device Epidemiology Group, Centre for Statistics in Medicine,

THE LANCET
Respiratory Medicine

Correspondence

Effectiveness of COVID-19 vaccines to prevent long COVID: data from Norway

Our recent study using data from m… than 20 million participants has sho… that COVID-19 vaccines consisten… prevent long COVID symptoms … adults, with meta-analytic calibrat… subdistribution hazard ratio (sH… of 0·54 (95% CI 0·44–0·67) in CP… GOLD, 0·48 (0·34–0·68) in CP… AURUM, 0·71 (0·55–0·91) in SIDI… and 0·59 (0·40–0·87) in CORIV… In addition, when consideri… post-COVID thromboembolic a… cardiovascular complications … outcomes of interest, recen… published data have shown th… vaccination with any COVID-19 fi… vaccine dose (ChAdOx1, BNT162… and mRNA-1273) is associat… with reduced risk of post-acu… heart failure (0·45 [0·38–0·5… 0–30 days after SARS-CoV… infection; 0·61 [0·51–0·73] 91–1… days after SARS-CoV-2 infectio… venous thromboembolis… (sHR 0·22 [95% CI 0·17–0·2… 0–30 days after SARS-CoV-2 infecti… 0·53 [0·40–0·70] 91–180 days af… SARS-CoV-2 infection), and arte… thrombosis (0·53 [0·44–0·6… 0–30 days after SARS-CoV-2 infecti…



In summary, we show the real-world effectiveness of COVID-19 vaccines to prevent long COVID symptoms and post-COVID thromboembolic and cardiovascular complications among the Norwegian population, consistent with previous findings from other countries (UK, Spain, and Estonia).[1,2] Additionally, we show the use of federated analytics applied across national borders to analyse linked real-world data mapped to the OMOP CDM. By applying publicly available scripts, we confirm the generalisability and reproducibility of two recent publications, strengthening their findings.

OHDSI Europe leading in clinical applications of patient-level prediction

International Journal of Colorectal Disease (2024) 39:31
https://doi.org/10.1007/s00384-024-04607-w

RESEARCH

Prediction of 30-day, 90-day, and 1-year mortality after colorectal cancer surgery using a data-driven approach

Karoline Bendix Bräuner[1] · Andi Tsouchnika[1] · Maliha Mashkoor[1] · Ross Williams[3] · Andreas Weinberger Rosen[1] · Morten Frederik Schlaikjær Hartwig[1] · Mustafa Bulut[1,2] · Niclas Dohrn[1,4] · Peter Rijnbeek[3] · Ismail Gögenur[1,2]

Accepted: 21 February 2024

Abstract

Purpose To develop prediction models for short-term mortality risk assessment following colorectal cancer surgery.

Methods Data was harmonized from four Danish observational health databases into the Observational Medical Outcomes Partnership Common Data Model. With a data-driven approach using the Least Absolute Shrinkage and Selection Operator logistic regression on preoperative data, we developed 30-day, 90-day, and 1-year mortality prediction models. We assessed discriminative performance using the area under the receiver operating characteristic and precision-recall curve and calibration using calibration slope, intercept, and calibration-in-the-large. We additionally assessed model performance in subgroups of curative, palliative, elective, and emergency surgery.

Results A total of 57,521 patients were included in the study population, 51.1% male and with a median age of 72 years. The model showed good discrimination with an area under the receiver operating characteristic curve of 0.88, 0.878, and 0.861 for 30-day, 90-day, and 1-year mortality, respectively, and a calibration-in-the-large of 1.01, 0.99, and 0.99. The overall incidence of mortality were 4.48% for 30-day mortality, 6.64% for 90-day mortality, and 12.8% for 1-year mortality, respectively. Subgroup analysis showed no improvement of discrimination or calibration when separating the cohort into cohorts of elective surgery, emergency surgery, curative surgery, and palliative surgery.

Conclusion We were able to train prediction models for the risk of short-term mortality on a data set of four combined national health databases with good discrimination and calibration. We found that one cohort including all operated patients resulted in better performing models than cohorts based on several subgroups.

We have a lot to be proud of,

but we shouldn’t be satisfied yet…

Selection of European Initiatives Using the OMOP CDM

Moderator: Renske Los, PhD, Assistant Professor of Medical Informatics, Erasmus MC

European Initiatives Using the OMOP CDM

1. **OHDSI Europe National Nodes building opportunities through collaboration**
   Renske Los, Erasmus MC, The Netherlands

2. **ONCOVALUE: Can Real-World Data Shape the Future of Health Technology Assessment in Oncology?**
   Andreas Henriksen, Copenhagen University Hospital, Denmark

3. **DigiONE: technical challenges and solutions to European cancer OMOP conversions from hospital EHR**
   Piers Mahon, DIGICORE, UK

4. **The PHEMS Project: New Strategies in Health Data Sharing**
   Sofia Bazakou, The Hyve, The Netherlands

5. **Ecraid: European Clinical Research Alliance on Infectious Diseases**
   Ankur Krishnan, Heidelberg University Hospital, Germany

6. **PHederation – the Federated Network of Pulmonary Hypertension Registries**
   Eva-Maria Didden, Actelion, a Johnson & Johnson Company, Switzerland

OHDSI Europe National Nodes: building opportunities through collaboration

Renske Los

Erasmus MC

What do these countries have in common?

National OHDSI nodes established in 2024!

EHDEN
EUROPEAN HEALTH DATA & EVIDENCE NETWORK

+

EUROPE

facilitate national and international collaboration

National Nodes

National Nodes

An OHDSI Europe National Node
is a collection of organizations
within a member country.

The Node builds on the strengths
of the stakeholders and scientific communities
of that country.

National Nodes














International collaboration

- Twice yearly meeting of node leads

- Current initiatives on European level:
  - The Drug Challenge: Inventory of drug vocabulary mappings
  - Cost Action Call proposal

What do these countries have in common?


UEFA
EURO2024
GERMANY
UEFA
EUROPEAN FOOTBALL
CHAMPIONSHIP
© UEFA 2022

OHDSI BELGIUM

Unifying Health Data Harmonization with Open Science

- June 2023
- **140** individuals
- **64** organizations
- **15** datapartners

Denmark

Start date: 2024-04-30

Leading Organization:
Center for Surgical Science, Zealand University Hospital

Members: 18

Organizations / data partners: 10

Estonia

EST. 29 JAN 2024

Sulev Reisberg, Raivo Kolde

University of Tartu

- Members: 23
- Organizations: 6
- Data partners: 1
- Promoting OMOP in a number of high-level events in Estonia

The German Node

founded in Spring

2021

Start Date

Michele Zoch
Research Asscociate,
University of Technology
Dresden

Ines Reinecke
Head of Data Integration Center
University Hospital
Dresden

Lead

Leading organization

University of Technology Dresden
Faculty of Medicine Carl Gustav Carus

Institute of Medical Informatics and Biometrie

Members

52

Universitätsklinikum Carl Gustav Carus

TECHNISCHE UNIVERSITÄT DRESDEN

MHH

CHARITÉ
UNIVERSITÄTSMEDIZIN BERLIN

MEDIZIN INFORMATIK INITIATIVE

mio42

ingef

IQVIA

data4life

... and many more

October,
28th and 29th

Save the Date

German Studyathon

OHDSI

GREECE OHDSI

OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

Start date: July 2021

Lead: Pantelis Natsiavas, Institute of Applied Biosciences, Centre for Research and Technology Hellas (INAB|CERTH)

- 5 data providers supported by EHDEN funding
- 3 universities/research centres
- 4 hospitals
- 11 private companies
- 5 certified organizations/SMEs by EHDEN
- 2 research programmes focusing on OMOP-CDM
- 1 innovation programme currently supporting ETL process
- 3 multi-national industries local branches on board
- Many dissemination activities (MSc programmes, online activities etc.)

Israel

- Node lead: Chen Yanover, KI Research Institute
- Kick-off meeting: May 20, 2024
- We had >50 attendees from most Israeli health organizations (hospitals, HMOs), government, academia, and industry
- Data partners: Kineret – OMOPed data of six government medical centers; more to come

OHDSI Italia

Active since **JUN 22**
Coordinated by **University of Pavia** & **BIOMERIS**
55+ people
33 institutions (**21** data partners)
Plenary meeting every 3 months + target meetings (e.g. DPO, protocols)

- **DPIA (Data protection Impact Assessment)** template for OMOP setup in a center
- **1st OHDSI Italia project**: two studies to evaluate whether partners are ready to participate in a study using OHDSI tools

1. Characterization of the national reality of the Italian node of OHDSI (using DQD and Achilles) ➔ 14 data partners involved
2. Correlates of hospital sepsis. A longitudinal cohort study of the Italian OHDSI Node (using Atlas and HADES) ➔ 10 data partners involved

OHDSI Luxemburg

Our mission is to redefine healthcare by harnessing real-world clinical data and experiences to empower clinicians and enhance patient well-being. We aim to shape the future of medical knowledge by also focusing on OMOP Common Data Model Medical Device Extension and on Patient Reported Outcome Measures (PROMs)

Start date: kicked-off December 12th, 2023

Leading organizations:

- Information Technology for Translational Medicine S.A. (ITTM S.A.)
- Luxembourg Institute of Health (LIH)

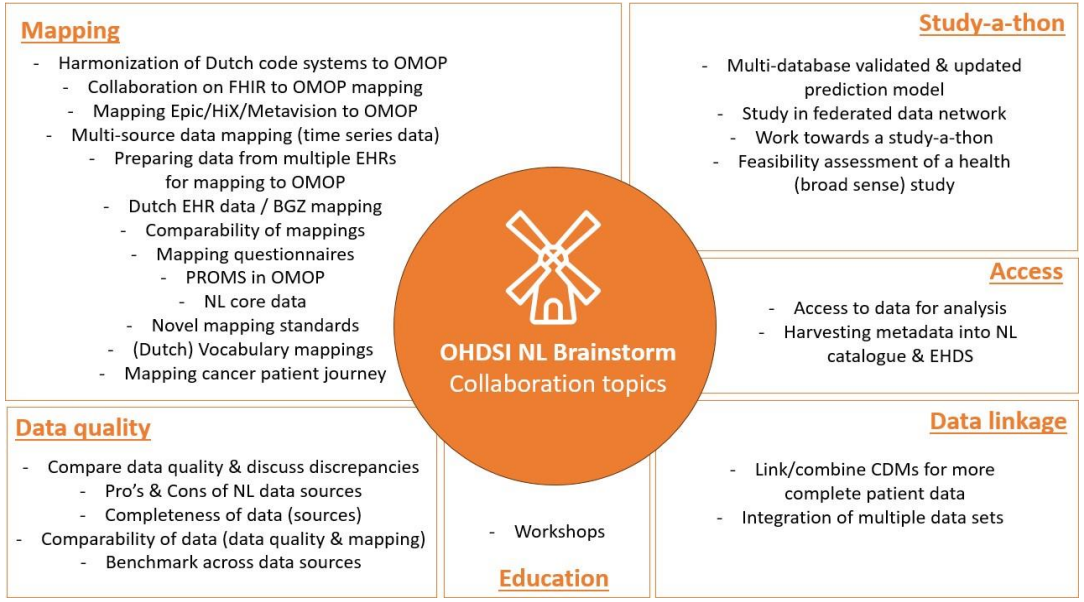
Members: Andreas Kremer (ITTM S.A.), Sebastiano La Ferla (ITTM S.A.), Rachelle Krajnc (ITTM S.A.), Loic Marx (ITTM S.A.), Romain Tching (ITTM S.A.), Nils Christian (ITTM S.A.), Maria Quaranta (ITTM S.A.), Maximilian Fünfgeld (LIH); Claudine Backes (LIH), David Marcic (LIH), Michaël Schnell (LIH), Guy Fagherazzi (LIH), Sophie Couffignal (LIH), Vanessa Pereira (LIH)

Data partners: National Cancer Register

OHDSI NL

- 61 members (+110%)
- 8 data partners
- ≈ 3 monthly meetings ('niet lullen maar poetsen')

Topics of interest:



Currently in progress:

Mapping BGZ (Dutch Int'l Patient Summary) from FHIR to OMOP

Study-a-thon characterization of breast cancer patients

NorOMOP

Espen Enerly, Siri Larønningen

Cancer Registry of Norway, part of Norwegian Institute of Public Health

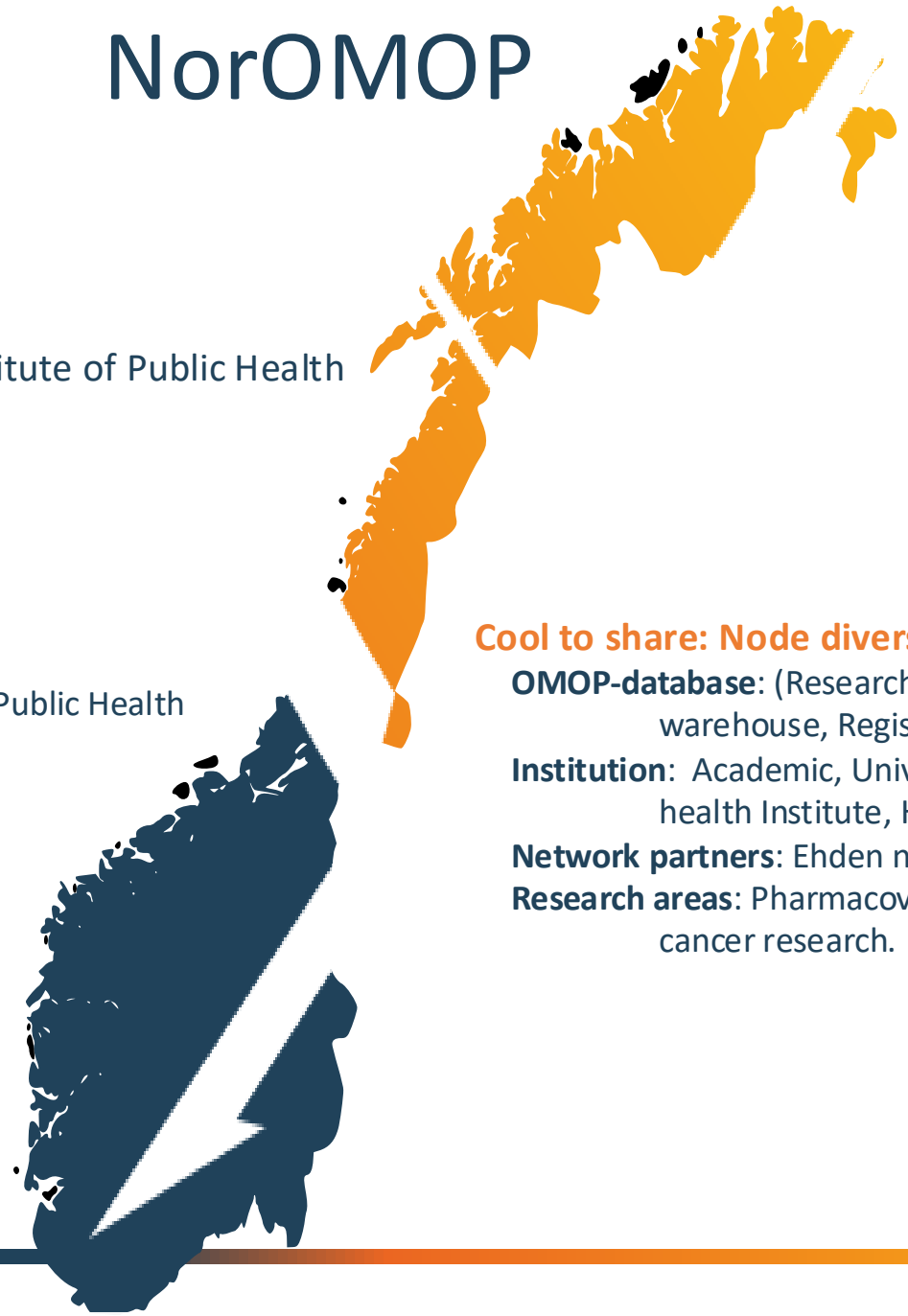
Start date: 10.10.2023

Data partners: 3

- Oslo University, Department of Pharmacy
- Oslo University Hospital
- Cancer Registry of Norway, Norwegian Institute of Public Health

Members organizations: 5

- Norwegian Directorate of Health
- Oslo University, Department of Pharmacy
- Oslo University Hospital
- Norwegian Institute of Public Health
  - Cancer Registry of Norway
  - Helsedata.no (Health Data Access Body)
  - Various departments



Cool to share: Node diversity

OMOP-database: (Research project, Hospital data warehouse, Registry)

Institution: Academic, University, National Registry/Public health Institute, Health Data Access Body

Network partners: Ehden network, Darwin-EU, DigiCore

Research areas: Pharmacovigilance, perinatal research and cancer research.

OHDSI Community

OHDSI Portuguese node

Portugal is at the forefront of this movement, and the formalization of the National OHDSI Node lays the foundation for a thriving community of Portuguese healthcare data partners and SMEs. **This community aims to foster interdisciplinary collaboration to discuss and address national healthcare challenges through real-world evidence.** The Node will also serve as a gateway for international innovation, research partnerships, and knowledge sharing around OMOP-CDM.

Leading Organization: ULS Coimbra

Data Partners

UNIDADE LOCAL DE SAÚDE COIMBRA

UNIDADE LOCAL DE SAÚDE GAIA E ESPINHO

apdp Diabetes Portugal

Hospital do Espírito Santo E.P.E. Évora

Reuma.pt

2CA Braga Centro Clínico Académico

Hospital de Santarém

LUZ SAÚDE

cuf

Instituto de Medicina Molecular | João Lobo Antunes

ULS Matosinhos

SMEs

promptly

Prologica Empowering People

MTG Real-World Evidence Implementation Science Scientific Consulting

Resilient End-to-end Scientific Consulting Services

OHDSI SPAIN
Activities and Plans

More than 25 data partners and SMEs (established in 2023)

Working Groups:

- Medications (led by the Spanish Medicines Agency)
- Costs (led by the Navarra Health Service and Hospital del Mar)
- LOINC (led by Hospital del Mar)

Meetings and Conferences:

- 2 ftf meeting and 2 online meetings
- Spanish Node presentations: Rotterdam 2023, INNODATA 23', and European Big DataVF 23'
- Study-a-thon planned for Q4 2024 in Barcelona

National Initiatives:

- RWD Cardiovascular Diseases: environmental + clinical data network – Carlos III Health Institute (Spanish Ministry of Health) (submitted)
- OHSIRIS - Open Health Space Infrastructure for Research and Industrial Services, Next Generation EU, Spanish Ministry of Digital Transformation (submitted)
- ELADAIS Project (Clinical and Omics data standardization using OMOP) – UNICO R&D Cloud Programme, Spanish Ministry of Digital Transformation (ongoing)

Coordinators: Talita Duarte-Salles (IDAPJordiGol) and Miguel Angel Mayer (Hospital del Mar)
Coordinator Assistant: Angela Leis (Hospital del Mar Research Institute)

OHDSI UK

Key achievements and directions

- We have a logo!
- Successful f2f annual meetings – 2nd event scheduled for September in London, with >100 attendees confirmed
- Formal support and partnership with HDRUK
- NHS England Secure Data Environments will be mapped to OMOP!
- National initiatives 'brewing':
  - HDRUK OMOP RWE Pilot Network – Oxford-led Coordination Centre funding agreed pending contract signature
  - Innovate UK Centre for Regulatory Sciences and Innovation – Partnership with 7 national partners shortlisted for funding to work with MHRA

Visit us!

La Fontaine – deck B

13.00 – 16.00

ONCOVALUE: Can Real-World Data Shape the Future of Health Technology Assessment in Oncology?

Andreas Henriksen

Copenhagen University Hospital

Oncovalue: Implementing value-based oncology care at European cancer hospitals

Mads Andersen[1], Juho Lähteenmaa[2], Johanna Mattson[2], Ulrik Lassen[1], Andreas Bjerrum[1]

[1]Department of Oncology, Rigshospitalet, Denmark, [2]IT Management and Comprehensive Cancer Center, Helsinki University Hospital, Finland

Andreas Henriksen

MD & PhD student

Department of Oncology, Rigshospitalet, Copenhagen, Denmark

Conflicts of interest:

Travel with Daiichi Sankyo

ONCOVALUE - Implementing value-based oncology care at European cancer hospitals
This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement No 101095245

oncovalue

Consortium of cancer centers & technology companies – funded by Horizon Europe

1.12.2022 – 30.11.2026
7 M€ total budget

HUS Helsinki University Hospital

Netherlands Cancer Institute – Antoni van Leeuwenhoek

Rijnstate

Region H – Rigshospitalet

IPO Porto – Instituto Português de Oncologia do Porto FG, EPE

Istituto Romagnolo per lo Studio dei Tumori Dino Amadori

Siemens Healthineers

BC Platforms

elevate

TTOPSTART

IQVIA™

CiaoTech

Oncovalue Mission

Aim

- Make available high quality Real-World Data for Health Technology Assessment
- Support development of effective treatment

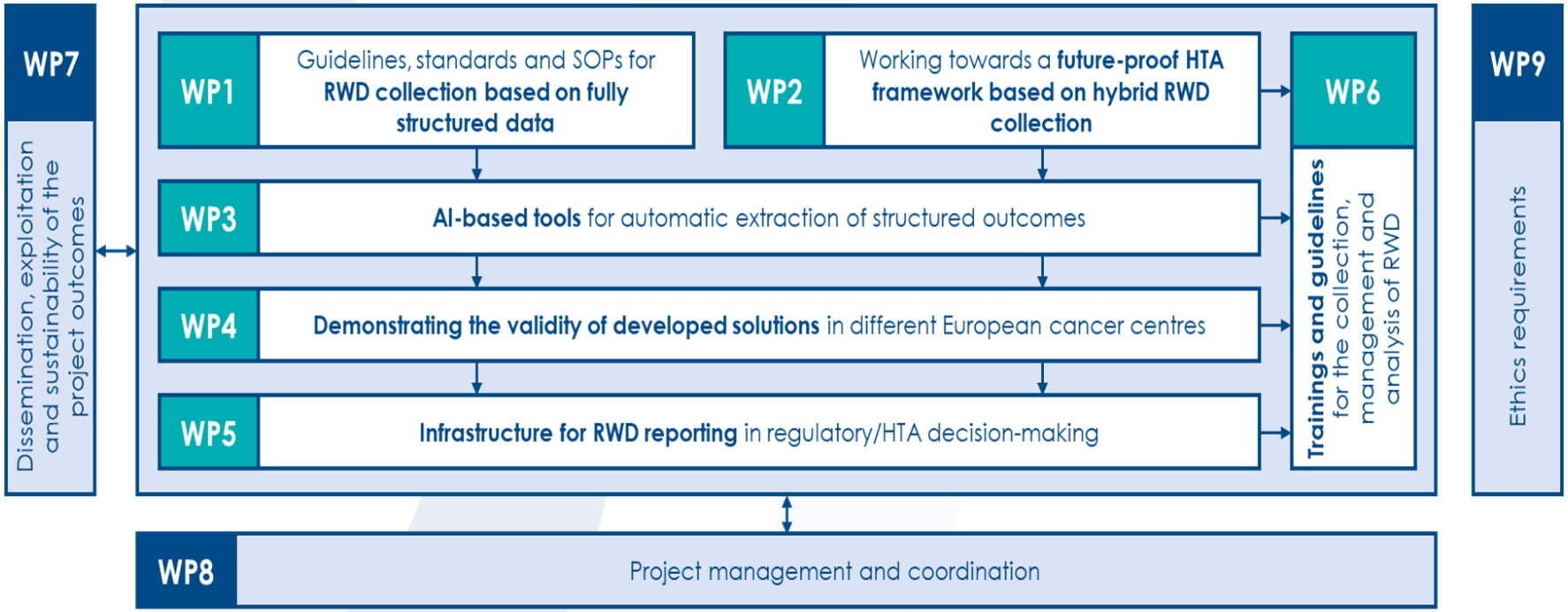
Background

- Efficacy-effectiveness gap in Randomized Clinical Trials
- Deficient toxicity reporting in phase IV trial setting
- High cost of novel treatments pose challenge to healthcare systems

oncovalue

Through 9 Work Packages, ONCOVALUE will

- Implement OMOP-CDM
- Develop federated analyses platform
- Utilize unstructured Electronic Health record data with AI-based tools



oncovalue

oncovalue

Thank you!

www.oncovalue.org

https://www.linkedin.com/company/oncovalue/

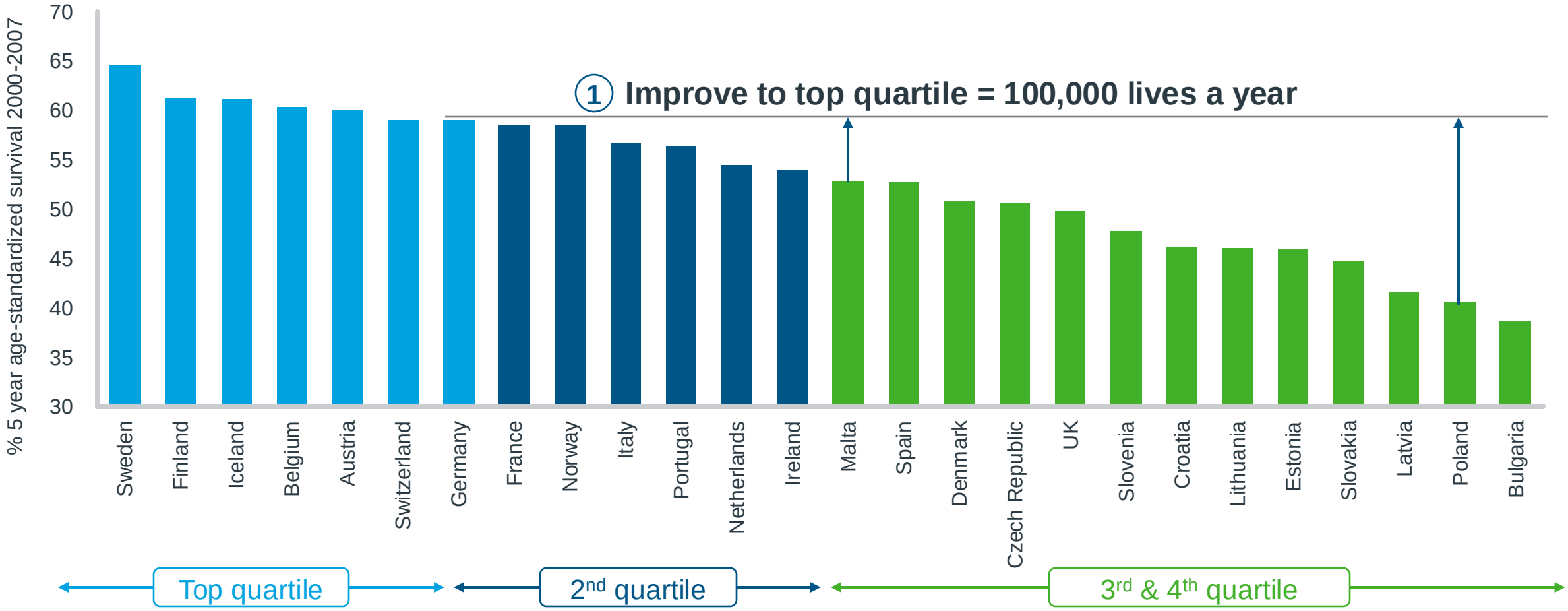
DigiONE: technical challenges and solutions to European cancer OMOP conversions from hospital EHR

Piers Mahon

DIGICORE

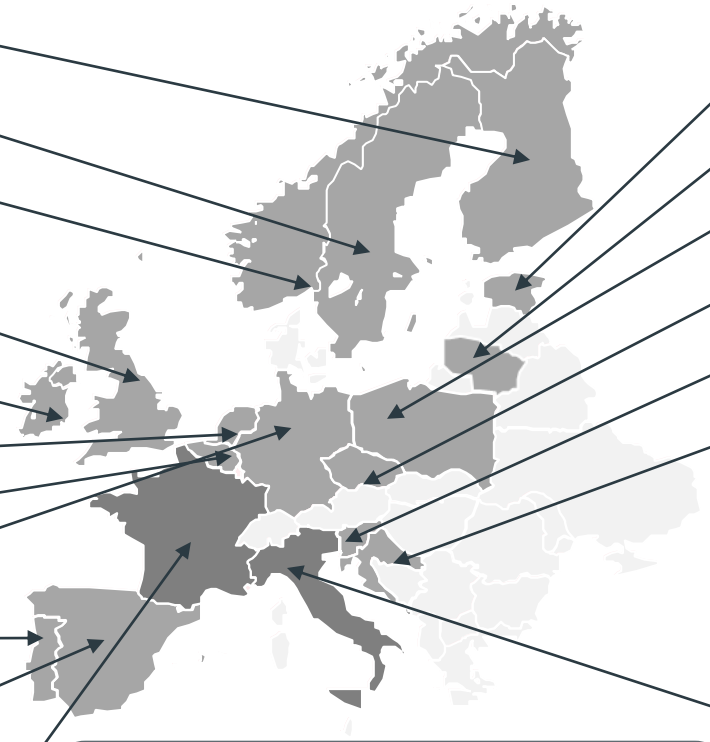
DIGICORE's Mission: reduce the variation in EU cancer outcomes digitally

National 5 year cancer survival, %



Source: EUROCARE-5 5-year survival by tumor and country based on 2000-2007

DIGICORE includes 37 cancer centres in 18 countries, 21 with Cancer OMOP instances built or funded and US / Asian extensions in planning



1. TAYS Cancer Centre

Vision Zero Cancer

2. Oslo UH

3. Edinburgh
4. Leeds
5. Trinity St James

6. Maastricht CCC
7. Saint Luc
8. UCC Frankfurt
9. IPO Porto
10 Fund. Jimenez Diaz
Start Madrid, Clínica Universitaria Navarra

Unicancer network (3)
Institut Curie,
Centre Léon Bérard,
Centre Jean Perrin

DigiONE I3 research partner (4)
11. Charite
12. Greiswald
13. Gronigen
14. Dresden

US and Asian centres in conversion planning

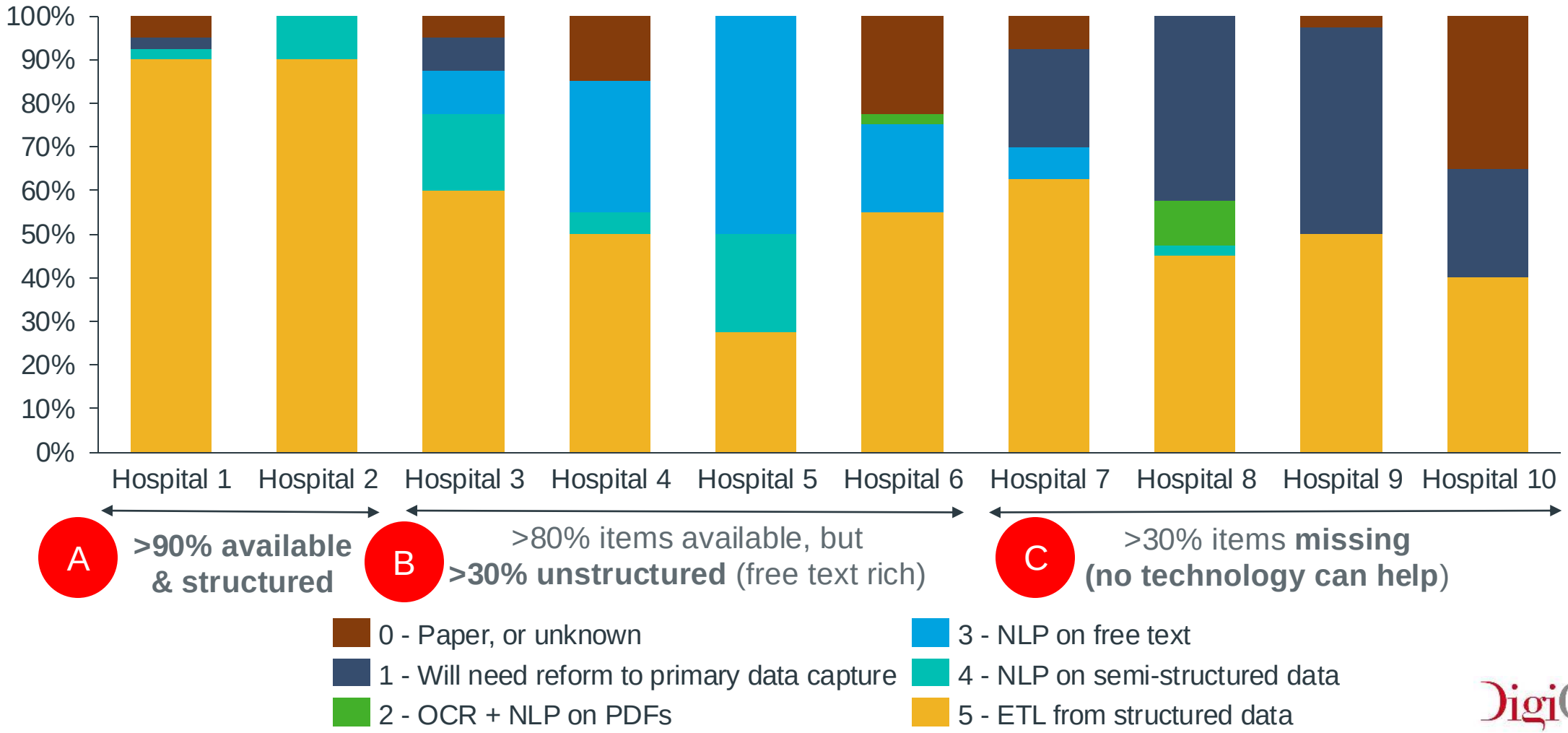
15. Tartu University Hospital
16. National Cancer Institute
17. Maria Skłodowska Curie
18. Masaryk Memorial
Inst of Oncology Ljubljana
Sestre Milosrdnice

ACC network (10)
IEO, 19. **INT Milan**,
Gemelli, Reggio Emilia
20 IRST, **21 San Raffaele**,
INT Pascale
IRCCS Veneto, San Matteo
Humanitas Mirasole

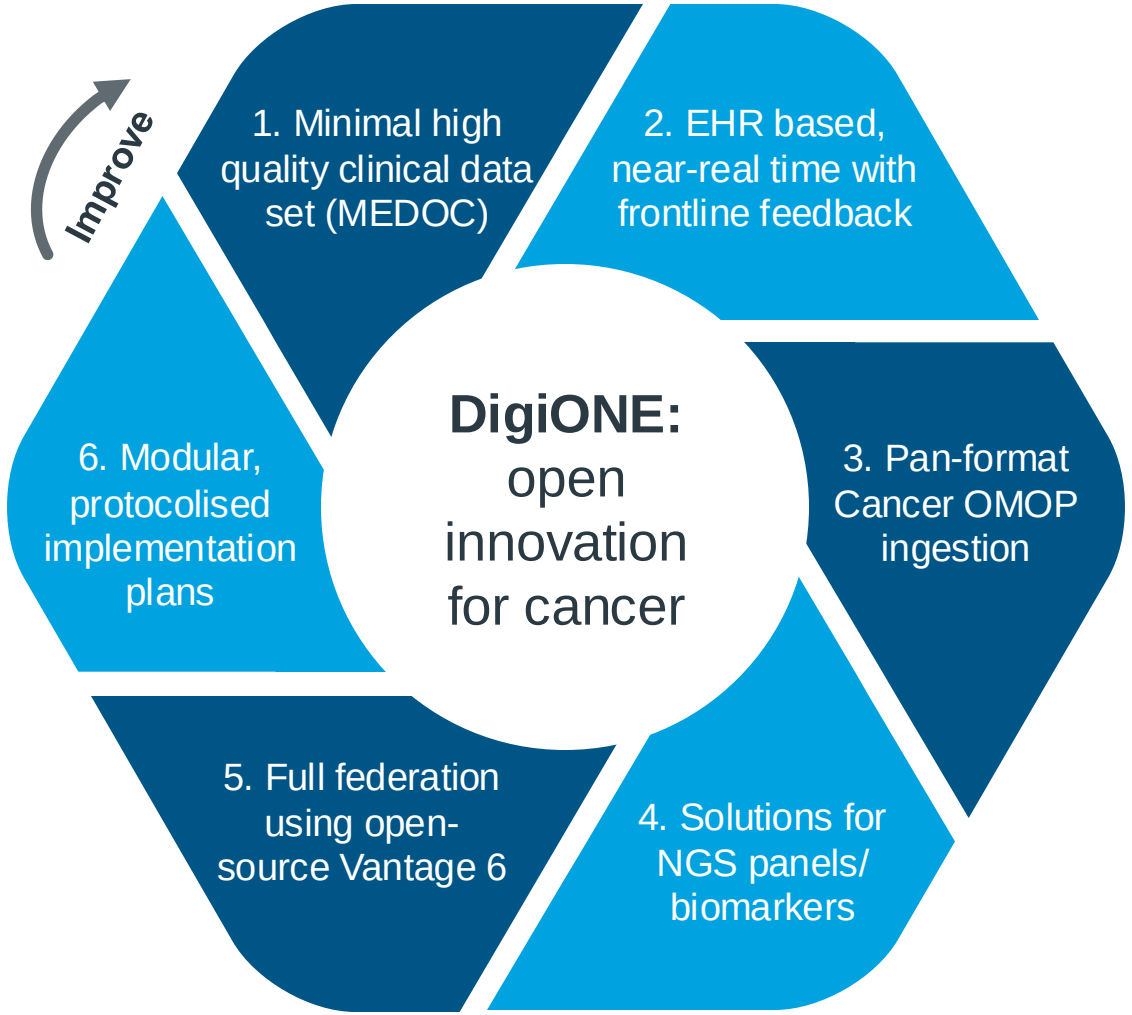
Key:
Bold - Cancer OMOP funded

Problem: Hospital data is challenging data – most will require NLP and primary data capture improvement, so it's expensive (EHDS take note..)

Data item availability *on* ***40 items agree by consensus*** *"essential for good care management" (%)*



The outline for DigiONE, our integrated, open standard technology stack was published in Nature Medicine, including a description of target data



1. **Minimal Essential Description Of Cancer** (MEDOC) Consensus built care quality minimal data set
2. **Near-real time frontline feedback loops** to improve data
3. **Pan-format Cancer data ingestion to OMOP**. Not just ETL also NLP, OCR
4. **GDPR recital 34 privacy conserving solutions for next generation sequencing results**
5. **Full federation with open source Vantage6** to allow statistical analysis equivalent to centralised data, but without data pooling and without patient consent
6. **Modular, protocolized implementation plans** to solve for limited data normalisation skills in most hospitals
7. **All in <u>open standards</u> and <u>vendor agnostic</u>**

Mahon, P., Chatzitheofilou, I., Dekker, A. et al. A federated learning system for precision oncology in Europe: DigiONE. Nat Med 30, 334–337 (2024)

DigiCore

We use Disease Natural History with care quality assessment to clean up large cohorts of patients, even in hospitals with weak legal basis

Example NSCLC Cohort

Patients diagnosed with mNSCLC between 1st November 2018 – 30th November 2023

- Subgroups by stage at diagnosis of NSCLC
  - De novo metastases
  - Initially diagnosed with NSCLC at earlier stage
- Subgroups with metastases at index date in:
  - Each of these single sites: Brain, liver, adrenal gland, bone, other lung, other single sites
  - Multiple sites: Including brain, excluding brain
- Subgroup prescribed immunotherapies as 1st LoT for mNSCLC

Research objectives summarised

1. Describe demographic and clinical characteristics, **genetic phenotype, re-biopsy rates**, and Tx received for NSCLC prior to index
2. Describe **SACT patterns by 1st and 2nd LoT, radiotherapy and surgery** for mNSCLC
3. Assess **OS and TtNT by 1st and 2nd LoT** incl. adjustment for prognostic characteristics
4. Describe **duration of Tx, starting dose, and dose intensity** by age and gender in patients prescribed **1st LoT immunotherapies** for mNSCLC
5. Benchmark **care quality** against ESMO guideline recommendations

DINASTY = clinical audit = legitimate use = legal to process anywhere

ESMO: European Society for Medical Oncology; LoT: Line of Therapy; mNSCLC: metastatic Non Small Cell Lung Cancer; OS: Overall Survival; SACT: Systemic Anti Cancer Treatment; TtNT: Time to Next Treatment; Tx: Treatment

DINASTY studies are just the first step on a longer journey to transform the impact of cancer real world evidence globally

THE WORLD TODAY	DINASTY STUDIES *(large scale data preparation)*	THE FUTURE… *(the exciting narrow cohort stuff)*

Traditional eCRF observational study

- Manual retype post-consent into central eCRF
- Statistical analysis of centralised pooled data

Join us!

Automate a cancer outcomes study

- Network wide Cancer OMOP study implementation
- Data “ready” before protocol in research environment
- Federation to get pooled data equivalent insights without pooling data

- Health system research
- Comparative effectiveness
- Patient finding / trial planning
- Pragmatic trial
- Safety ascertainment
- Discovery – omics
- Biomarker validation
- Care quality management
- AI driven Decision Support

Key: Research users

- Pharma RWE/Med affairs
- Pharma clinical dev/R&D
- Diagnostics companies
- National governments

The PHEMS Project: New Strategies in Health Data Sharing

Sofia Bazakou

The Hyve

phems

New Strategies in Health Data Sharing

Sofia Bazakou, sofia@thehyve.nl

Pediatric Hospitals as European drivers for Multi-party computation and Synthetic data generation capabilities across clinical specialties and data types

3 years

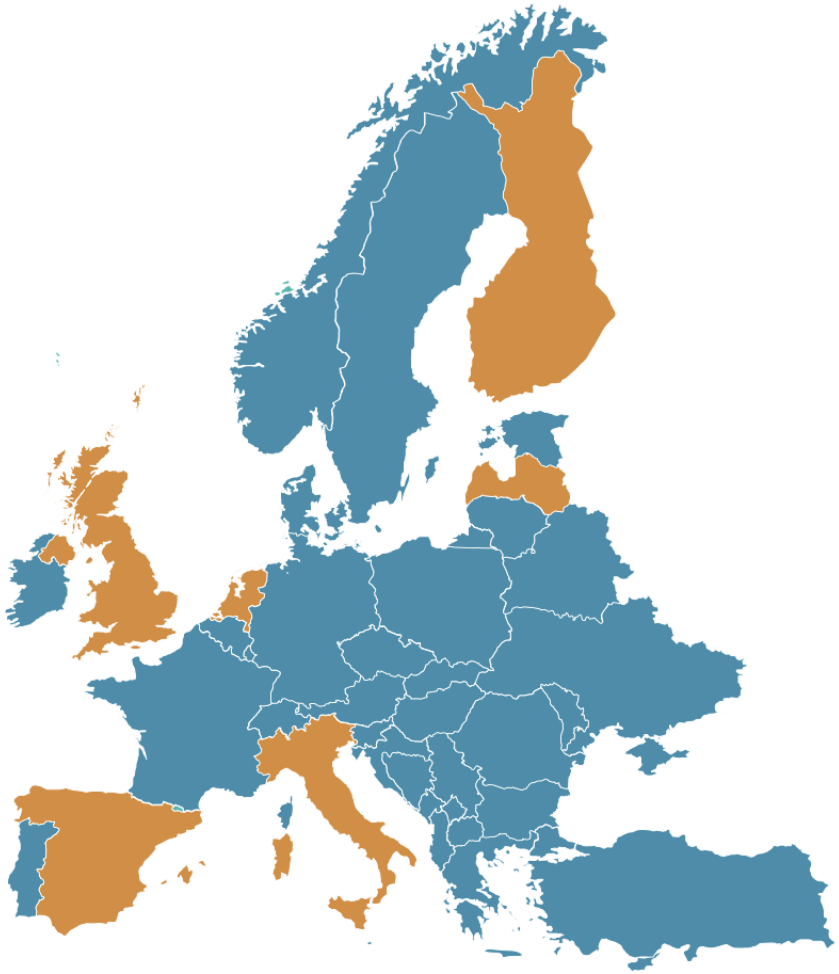
October 2023 - September 2026

7 M€

Funded through Horizon Europe and UK Research & Innovation

Coordinated by HUS Helsinki University Hospital

The clinical cases use pediatric data stored in the OMOP Common Data Model (CDM)



Funded by the European Union

UK Research and Innovation

phems

PHEMS transcends boundaries, supporting access and use of health data between children's hospitals and across borders

Objectives

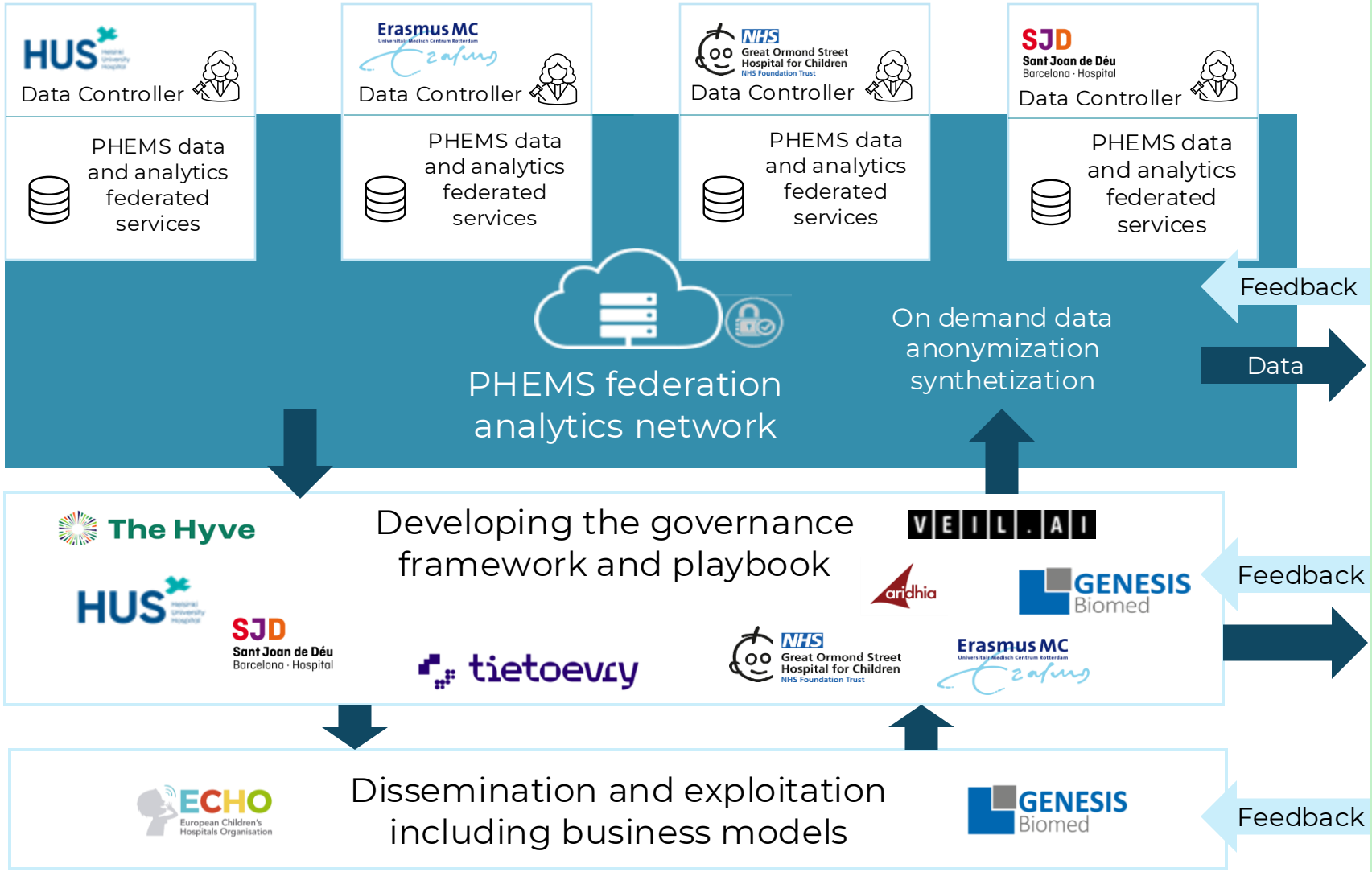
- Increase access to health data while protecting patient privacy
- Advance federated health data analysis through predictive modelling and machine learning
- Enable on-demand generation of shareable synthetic and anonymized datasets
- Demonstrate the value of the data ecosystem using three clinical use cases in four countries

The project will create a **decentralized and open health data ecosystem** consisting of **technical components** and **governance frameworks**, empowering institutions to **collaborate without relinquishing control** over their data.

phems

Funded by the European Union

Project Overview



Funded by the European Union

Validating the results

Clinical validation of synthetic data vs. raw data

Clinical Use case 1: Cardiology patients operation management

Clinical Use case 2: Pediatric Intensive Care Unit (PICU) Sepsis

Clinical Use case 3: Hematology; hemophilia

Validation of governance framework and playbook

Meyer Azienda Ospedaliera Universitaria

Children's University Hospital Latvia

Evaluating the business models and accessibility through Hackathons

GENESIS Biomed

SJD Sant Joan de Déu Barcelona · Hospital

Find out more

Clinical Use Cases

PHEMS: **validating novel federated ecosystems** for analytics and **synthetic data generation** methods through real-world data investigations, particularly in the context of **pediatric healthcare**

New strategies in Health Data Sharing – Clinical Use Cases

Pediatric Hospitals as European drivers for multi-party computation and synthetic data generation capabilities across clinical specialties and data types (PHEMS, an EU-funded project) aims to establish an open and decentralized health data ecosystem for accessing health data across multiple European hospitals. Data federation (federated analytics and learning) will be applied to overcome significant obstacles in cross-border collaboration while complying with the European Union's General Data Protection Regulations (GDPR). Additionally, PHEMS will develop an innovative data synthesis and anonymization pipeline for use in the federated ecosystem to increase the statistical power for rare disease research.

Variable categories

The variables of interest for each use case are further grouped into categories.

Bleeding Complications Surgery Procedures PhysicalExamination Diagnosis VitalSigns Demographics Clinical LabMeasurements Treatment Additional LengthOfStay Hospitalisation

Variable overlap

An overview of the number of variables to be collected for each use case and their overlap.

Use Case 1 Use Case 2 Use Case 3

180 (45%) 40 (10%) 139 (35%) 8 (2%) 6 (1%) 1 (0%) 29 (7%)

1 Cardiology operations benchmarking

Supporting **creation of benchmarking standard** and **promote a culture of benchmarking** across pediatric cardiac institutions, enabling **the adoption of 'best-practice' across institutions**

Led by Great Ormond Street Hospital for Children (GOSH)

2 Pediatric Intensive Care Unit Sepsis

Investigating the benefits of the federated ecosystem to **develop, train and test algorithms to predict sepsis** on a large scale between pediatric intensive care units in four large European children's hospitals

Led by Sant Joan de Déu Barcelona Children's Hospital (HSJD)

3 Hematology - hemophilia

Developing and testing a machine learning-based prediction algorithm to improve treatment for pediatric patients with **hemophilia A or B**

Led by Erasmus University Medical Centre Rotterdam (Erasmus)

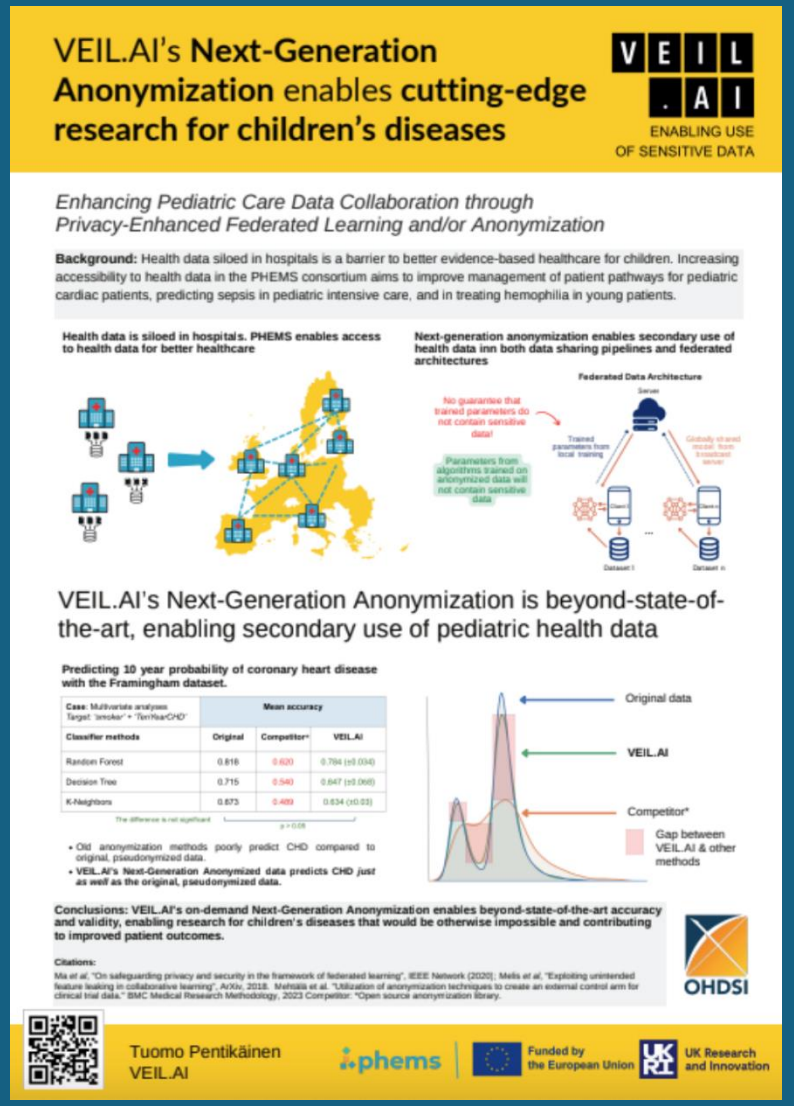
At the current state of the project, the achievement worth mentioning is the curation of the variables essential to the use case studies. This preliminary work, in the first months of the consortium, lays the foundation for the OMOP data standardization at the hospitals and the synthetic data generation.

OHDSI

Sofia Bazakou, Lydia Briggs, Marinel Cavelaars, Roger Domingo Espinos, Aida Felipe Villalobos, Katarina Gehrmann, Liam Glueck, Iolanda Jordan Garcia, Jan Willem Kuiper, Jennifer McIntosh, Cristina Ruiz Herguido, Andrew Taylor, Marja Vatinen, Arnau Valls Esteve, Gary Zhen Yuan Liew, Asadeh Tafreshiha, Guus Wilmink

phems Funded by the European Union UK Research and Innovation The Hyve Erasmus MC Cancer Institute HUS SJD Sant Joan de Déu Fundació de Recerca ECHO SJD Sant Joan de Déu Barcelona Hospital

Data anonymization and synthetization



VEIL.AI's **Next-Generation Anonymization** enables **cutting-edge research for children's diseases**

VEIL.AI ENABLING USE OF SENSITIVE DATA

Enhancing Pediatric Care Data Collaboration through Privacy-Enhanced Federated Learning and/or Anonymization

Background: Health data siloed in hospitals is a barrier to better evidence-based healthcare for children. Increasing accessibility to health data in the PHEMS consortium aims to improve management of patient pathways for pediatric cardiac patients, predicting sepsis in pediatric intensive care, and in treating hemophilia in young patients.

Health data is siloed in hospitals. PHEMS enables access to health data for better healthcare

Next-generation anonymization enables secondary use of health data inn both data sharing pipelines and federated architectures

Federated Data Architecture

No guarantee that trained parameters do not contain sensitive data!

Parameters from algorithms trained on anonymized data will not contain sensitive data

Trained parameters from local training

Server

Dataset 1 Dataset n

VEIL.AI's Next-Generation Anonymization is beyond-state-of-the-art, enabling secondary use of pediatric health data

Predicting 10 year probability of coronary heart disease with the Framingham dataset.

Case: Multivariate analyses Target: 'smoker' + 'TenYearCHD'	Mean accuracy		
Classifier methods	**Original**	**Competitor***	**VEIL.AI**
Random Forest	0.816	0.620	0.784 (±0.034)
Decision Tree	0.715	0.540	0.647 (±0.068)
K-Neighbors	0.673	0.489	0.634 (±0.03)

The difference is not significant $p > 0.05$

- Old anonymization methods poorly predict CHD compared to original, pseudonymized data.
- **VEIL.AI's Next-Generation Anonymized data predicts CHD *just as well* as the original, pseudonymized data.**

Original data

VEIL.AI

Competitor*

Gap between VEIL.AI & other methods

Conclusions: VEIL.AI's on-demand Next-Generation Anonymization enables beyond-state-of-the-art accuracy and validity, enabling research for children's diseases that would be otherwise impossible and contributing to improved patient outcomes.

OHDSI

Citations:

Mia *et al*, "On safeguarding privacy and security in the framework of federated learning", IEEE Network (2020); Melis *et al*, "Exploiting unintended feature leaking in collaborative learning", ArXiv, 2018. Mehtälä et al. "Utilization of anonymization techniques to create an external control arm for clinical trial data." BMC Medical Research Methodology, 2023 Competitor: *Open source anonymization library.

Tuomo Pentikäinen VEIL.AI

phems Funded by the European Union UK Research and Innovation

phems

Funded by the European Union

UK Research and Innovation

Ecraid: European Clinical Research Alliance on Infectious Diseases

Ankur Krishnan

Heidelberg University Hospital

ECRAID-Base

Building a European clinical research alliance on infectious diseases

Presented by: Ankur Krishnan
On behalf of the Ecraid consortium

ecraid
Base

The ECRAID-Base project has received funding from the European Union's Horizon 2020 Research and Innovation programme, under the Grant Agreement number 965313.

Ecraid: European Clinical Research Alliance on Infectious Diseases

- **ECRAID-Base** is a **'warm-base' pan-European clinical research network** that facilitates faster, easier and cost-effective **infectious diseases (ID) and antimicrobial resistance (AMR) research** to reduce their impact on individual and population health in Europe.

- ECRAID-Base addresses **ID outbreak preparedness and response** through efficiently and effectively generating rigorous evidence to **improve the diagnosis, prevention and treatment of infections**

- This is facilitated by a **European multidisciplinary clinical research network** and innovative research approaches. The network has the capacity and capability to:
  - directly enrol patients with infectious diseases to generate evidence to support the testing and development of new diagnostic, preventive and/or therapeutic strategies and therapies
  - conduct a broad range of rigorous clinical studies efficiently and rapidly
  - function as a platform for a rapid research response in the face of serious infectious disease outbreaks

Consortium

19 organisations based in ten countries: Belgium, Croatia, Czech Republic, Italy, Germany, France, the Netherlands, Spain, Switzerland, and the United Kingdom.

ecraid

UMC Utrecht

Universiteit Antwerpen

ecrin

Hospital Universitario Virgen Macarena

icnarc

Erasmus MC

University of Oxford

CHU Limoges

Università di Verona

University Hospital for Infectious Diseases "Dr. Fran Mihaljević"

Inserm

Université de Genève

Universitäts Klinikum Heidelberg

Amsterdam UMC

Penta Child Health Research

ERS European Respiratory Society — every breath counts

ESCMID European Society of Clinical Microbiology and Infectious Diseases

ecraid Network

Network of experts in epidemiology of infectious diseases and in the design of clinical studies, statistical methods and analyses

CLIN-Net	**Network of clinics and hospitals** capable of quickly and reliably recruiting, treating, monitoring and reporting data for multinational, multicenter studies
LAB-Net	**Network of microbiology laboratories** delivering high-quality and standardized information on microbial strains and antibiotic resistance
STAT-Net	**Network of statistics and clinical study design experts** in infectious diseases (ID) and antimicrobial resistance (AMR) research
EPI-Net	**Network of ID/AMR epidemiology and surveillance experts**
Penta ID	Network devoted to advancing research on optimising the **prevention, diagnosis and treatment of infectious diseases in children and in pregnancy**

900 labs - 42 countries

300 primary care sites - 18 countries

90 sites - 18 countries

1251 hospitals

27 Ecraid Clinical Liaisons

45 sites - 11 countries

Perpetual Observational Studies (POS)

Ventilator-Associated Pneumonia in ICUs	**POS-VAP** Started - August 2022 2967 participants enrolled Across 40 sites
Complicated Urinary Tract Infections in Hospitals	**POS-cUTI** Started - October 2022 2359 participants enrolled Across 43 sites
Acute Respiratory Infections in Emergency Rooms	**POS-ARI-ER** Started - June 2023 796 participants enrolled Across 42 sites
Acute Respiratory Infections in Primary Care	**POS-ARI-PC** Started - February 2024 62 participants enrolled Across 11 sites
Unexplained febrile illness with unusual epidemiology and/or clinical presentation in Emergency Rooms	**POS-Disease X** Started - December 2023 10 participants enrolled Across 8 sites
Community-Acquired Pneumonia in Hospitals	**REMAP-CAP (Europe)** Started - March 2018 7928 participants enrolled Across 131 sites

The first studies to benefit from Ecraid's infrastructure are -

- Five Perpetual Observational Studies (POS)
- European arm of the REMAP-CAP adaptive platform trial

A POS is a prospective, multicentre, observational clinical study that perpetually enrolls patients

They address key clinical research gaps, including variations in clinical practices, incidence of ID syndromes, and associated risk factors.

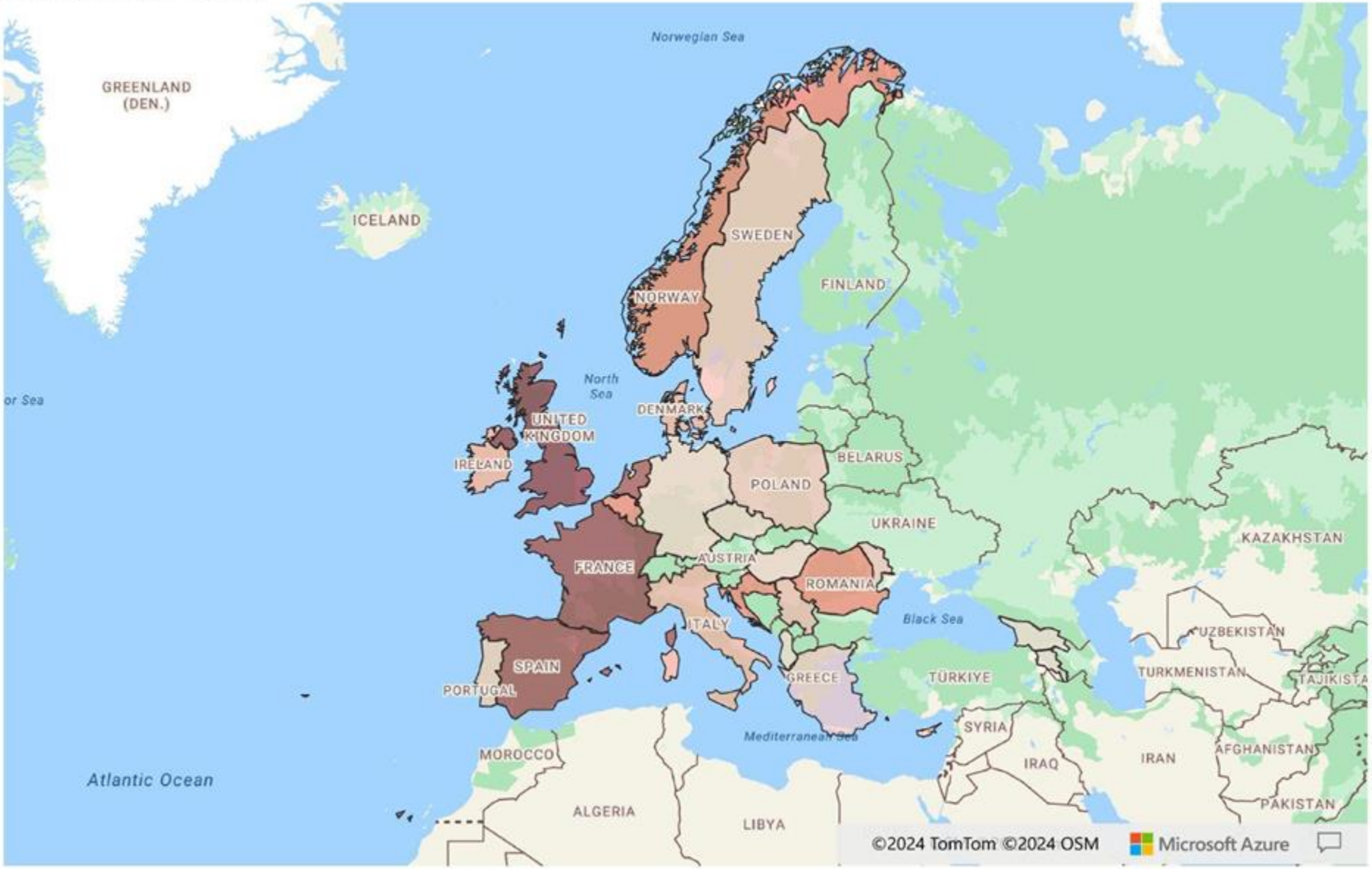
They create a clinical research backbone, ready to concurrently or sequentially embed studies (observational, experimental, investigator-initiated, or commercial)

Recruitment per country

24-5-2024 05:10

Data last updated

Active sites per country



Country	# Active sites	# Participants
United Kingdom	22	901
France	20	1563
Spain	19	1238
Netherlands	18	696
Norway	12	172
Belgium	11	648
Croatia	11	382
Romania	11	485
Denmark	7	176
Ireland	7	304
Italy	6	264
Serbia	5	810
Moldova	4	200
Poland	4	200
Sweden	4	118
Greece	3	181
Portugal	3	155
Cyprus	2	97
Czech Republic	2	203
Germany	2	178
Hungary	2	150
Albania	1	20
Armenia	1	206
Georgia	1	205
Total	**178**	**9552**

Our OHDSI journey till now…

Joined through the **EHDEN 5th Open Call**

Partnered with **edenceHealth NV** to transform POS-VAP data to OMOP-CDM

Established **a scalable, sustainable and secure architecture to deploy and maintain ETL pipelines and OHDSI tooling for ECRAID-Base** at UMC Utrecht (please visit our poster #13 for more details)

Leveraged the Oncology extension (OMOP-CDM v5.4) to map hierarchical and inter-event dependent patient-level data on microbiological identification and cure, AMR profiles, VAP clinical criteria based onset and clinical cure.

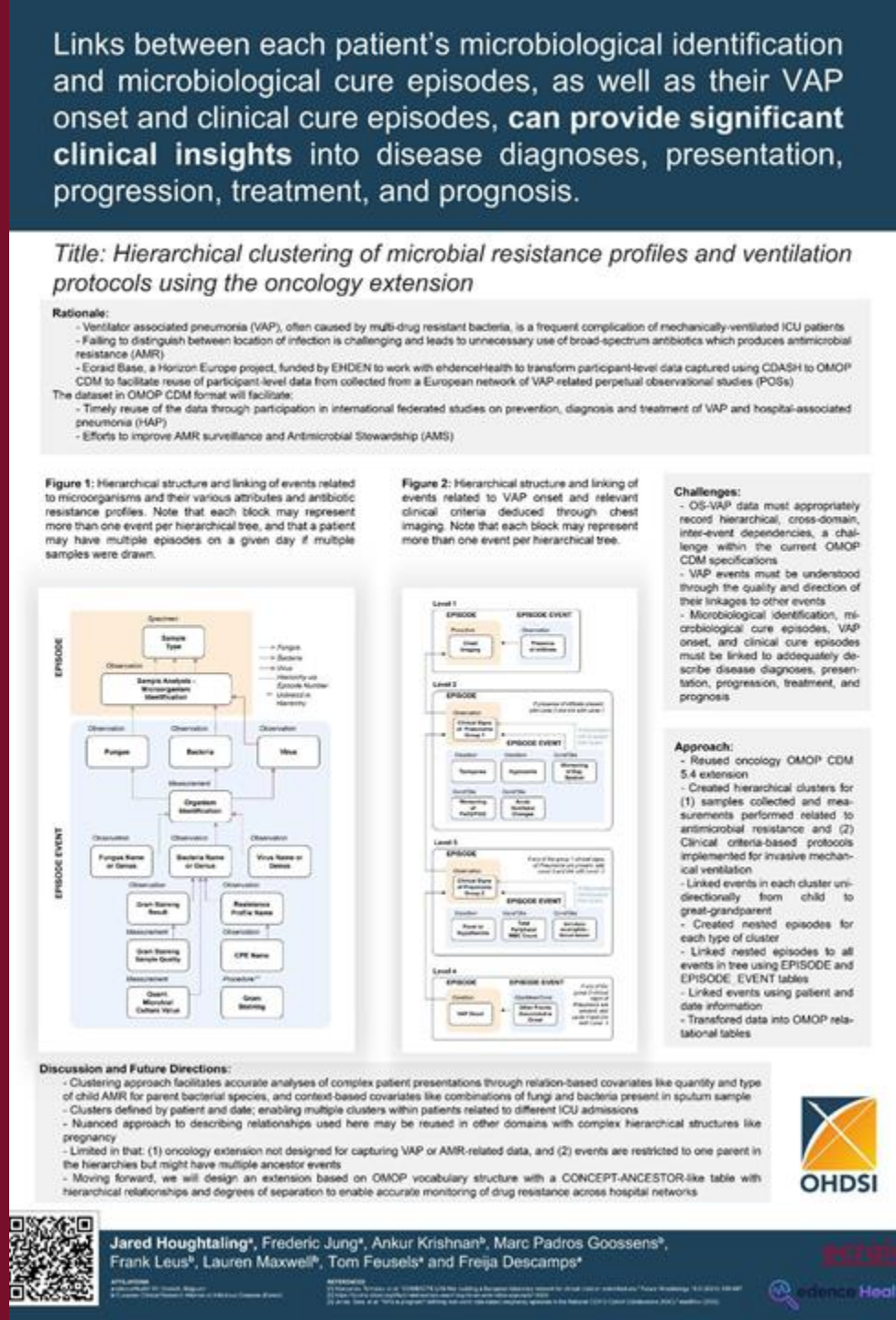
Successfully set up all infrastructure requirements for ETL validation (ACHILLES, DQD, ARES, ATLAS).

Published the data source on the **EHDEN Database Catalogue** (**'ECRAID-Base POS VAP'**)

Submitted an Expression of Interest to become a **DARWIN EU data partner**

ECRAID-Base metadata published on **EMA RWD catalogues** (Data source ID - 1111205)

Executed **MoU between Ecraid and EHDEN** foundations



Next steps and future directions

Continue transformation of the **remaining POSs to OMOP-CDM** through CoMeCT project

Train and educate the researchers and clinicians in our consortium on OMOP-CDM and OHDSI suite of tools and packages

Participate in OHDSI working groups (Common Data Model, CDM vocabulary subgroup, Registry, Natural Language Processing, Clinical Trials, Patient-level Prediction, Phenotype Development and Evaluation)

Leverage ECRAID-Base study data in OMOP-CDM, established infrastructure and partnerships with EHDEN, OHDSI and DARWIN EU communities to **participate in and initiate projects and studies on** -

- **Diagnosis, prevention and treatment of infections**
- **Infectious diseases epidemiology and antimicrobial resistance surveillance**
- **Pandemic preparedness and response**
- **Antimicrobial Consumption (AMC)** and **Antimicrobial Stewardship (AMS)**
- And, many more…

Initiate an **ID-AMR working group** to develop mapping guidelines and best practice recommendations

Identify a core AMR data structure that harmonizes the various potential sources of AMR data (EHR, LIMS, Cohorts, etc.)

Collaborate to develop a 'Microbiology extension', which leverages and builds upon the hierarchical structure in 'Oncology extension' and incorporates the nuances and complexities of ID/AMR research data

Thank you for your attention!

Got a question?

Please get in touch with me during the symposium

Visit our website - https://www.ecraid.eu/

Or, please reach out to me at - ankur.krishnan@uni-heidelberg.de

ecraid
Base

The ECRAID-Base project has received funding from the European Union's Horizon 2020 Research and Innovation programme, under the Grant Agreement number 965313.

PHederation – the Federated Network of Pulmonary Hypertension Registries

Eva-Maria Didden, Actelion, a Johnson & Johnson Company

PHederation™

The federated network of Pulmonary Hypertension registries

Presenter: Eva-Maria Didden
Co-authors: Valerie van Baalen, Michel van Speybroeck, Monika Brand
Date: June 3, 2024
Location: European OHDSI Symposium, SS Rotterdam, the Netherlands

Johnson&Johnson
Innovative Medicine

Background

- Pulmonary Arterial Hypertension (PAH) is a rare subgroup of Pulmonary Hypertension (PH).
- Real-World Evidence (RWE) generation in rare diseases is often restricted due to the small patient numbers, geographic distribution, and limited data access.
- In disease-agnostic EHR or insurance claims databases, it is challenging to accurately identify PH or PAH patients.
- PHederation is a disease-specific Federated Data Network (FDN) that brings together multiple fit-for-purpose PH data sources.

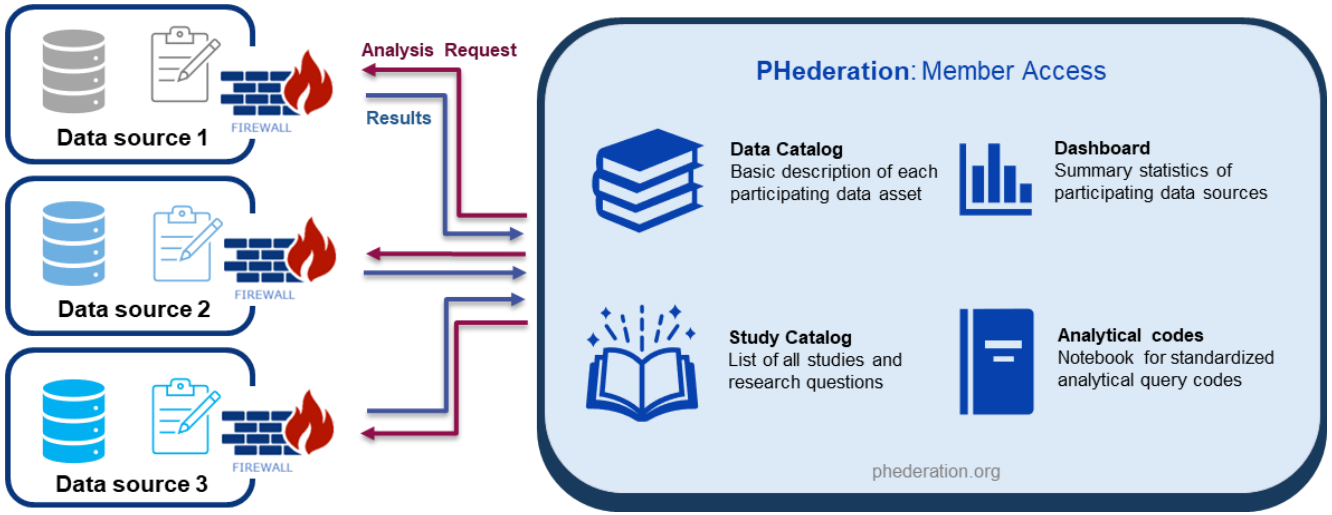
Introduction

PHederation is a public-private partnership

connecting* harmonized disease-specific clinical data sources and subject matter experts,**

for enhanced research in Pulmonary Hypertension.

➔ PHederation will contribute to an increase in transparency and reproducibility of RWE in PH***.



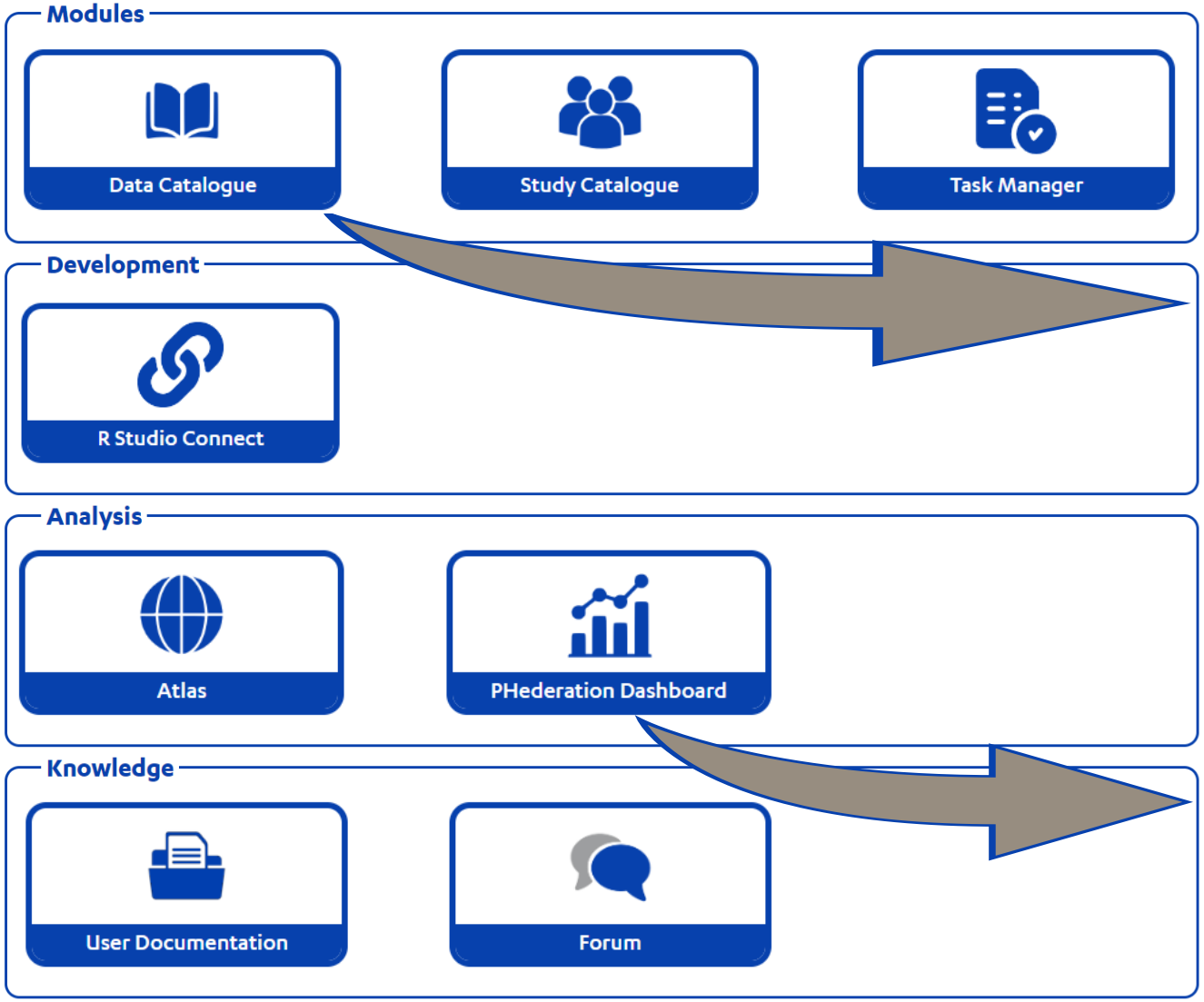
* Feder8 federative networks community: https://www.ohdsi-europe.org/images/symposium-2023/presentations/01_-_Morning.pdf

** A) Standardizing PH registry data to the OMOP Common Data Model: https://pubmed.ncbi.nlm.nih.gov/34727871/

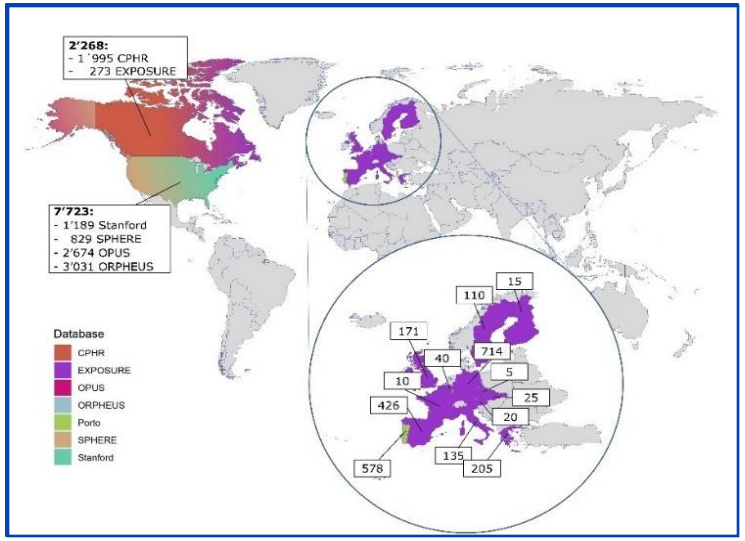
B) Handbook for PH registries to OMOP CDM conversion: https://github.com/OHDSI/ETL--PulmonaryHypertensionRegistries

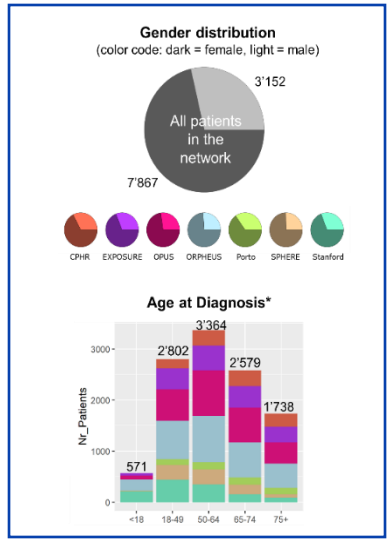
*** Increase transparency and reproducibility of RWE in rare diseases through disease-specific FDNs: https://pubmed.ncbi.nlm.nih.gov/38556812/

PHederation Portal



DATABASE	Description	Observation period	# PH and #PAH patients	Regions	Source data
Canadian PH Registry (CPHR)	Prospective PH patient registry	2017 - ongoing	PH – 1´995 PAH – 1´076	Canada	PAHTool
EXPOSURE (EUPAS19085)	Registry of PAH patients newly treated with Uptravi or another PAH-specific therapy	2017 - ongoing	PAH – 2'354	Europe, Canada	CDISC SDTM
OPUS (NCT02126943)	Opsumit drug registry	2014 - 2018	PH – 2'674 PAH – 2'208	USA	CDISC SDTM
ORPHEUS (NCT03197688)	Opsumit user medical chart review to supplement OPUS	2013 - 2017	PH – 3'031 PAH – 2'410	USA	CDISC SDTM
Porto center of Portuguese PH network	Northern Region Portuguese PH registry	2001 - ongoing	PH – 578 PAH – 216	Portugal - Northern Region	PAHTool
SPHERE (NCT03278002)	Selexipag drug registry	2016 - 2020	PH – 829 PAH – 759	USA	Registry-specific
Stanford clinical PH database	PH Registry	2004 - ongoing	PH – 1´189 PAH – 987	USA – Western Region	Registry-specific

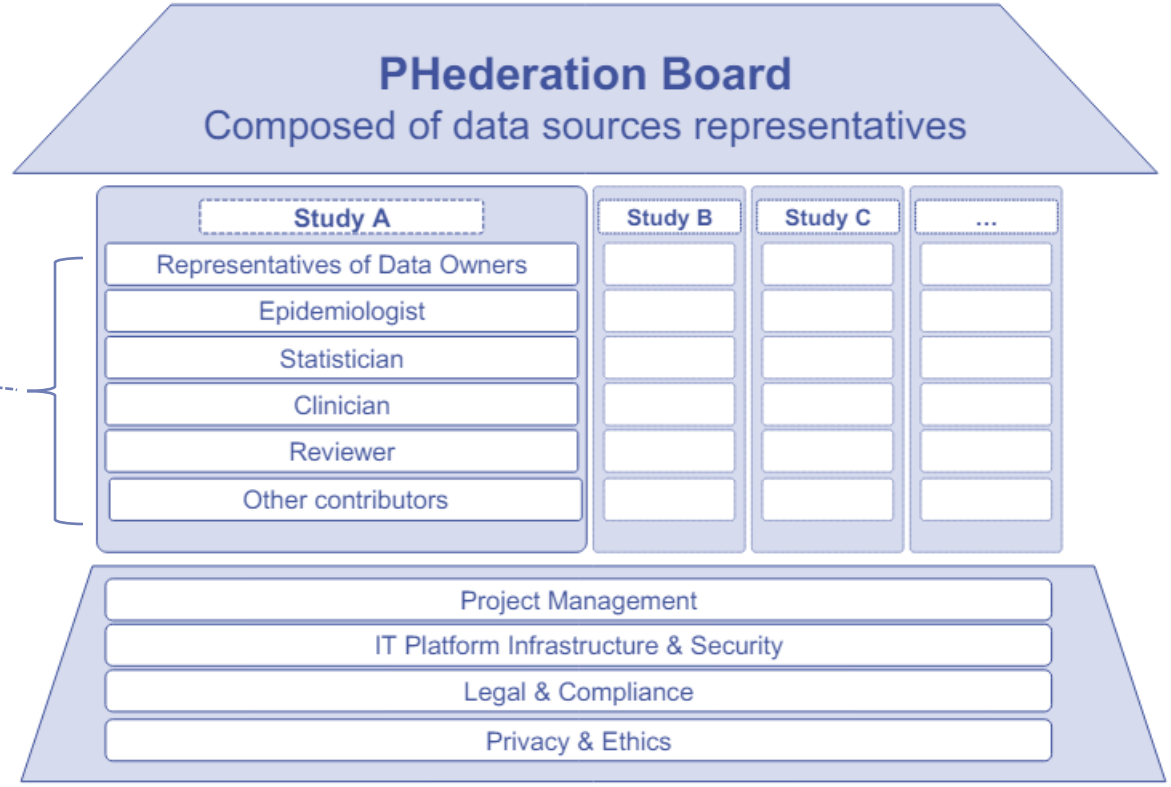




Study Conduct

1. Select databases using *Data Catalog* and *Dashboards*; perform fit-for-purpose evaluations.
2. Create study team to develop protocol and analysis plan.
3. Translate analysis plan into standard queries.
4. Distribute queries, execute analysis, and collect aggregate results; potentially conduct meta-analysis.
5. Interpret results, write study report, publish.

Governance



Conclusion & Outlook

PHederation established a network of databases of diverse purpose and origin:

- with the goal of advancing scientific knowledge in PH through distributed data sources and analytics, harmonization, and automation.
- to expand the breadth and depth of individual PH databases, to increase diversity and geographic coverage, and to accelerate and enhance RWE generation.

Visit us at PHederation.org !

First PHederation network study (ongoing): Drug utilization of endothelin receptor antagonists and phosphodiesterate-5 inhibitors in newly-diagnosed PAH patients.

This study will complement Darwin EU's EUPAS106052* with evidence from a disease-specific FDN.

* EUPAS106052: https://catalogues.ema.europa.eu/node/3797/administrative-details


Improve the care for patients
with Pulmonary
Hypertension with the
power of real-world data

Coffee break!

Next session starts here @ 11:30!