Journal Club:
11th Revision of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology

OHDSI Community Call
Sept. 19, 2023 • 11 am ET
# Upcoming Community Calls

<table>
<thead>
<tr>
<th>Date</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sept. 19</td>
<td>Journal Club: 11th Revision of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology</td>
</tr>
<tr>
<td>Sept. 26</td>
<td>Publications Presentation</td>
</tr>
<tr>
<td>Oct. 3</td>
<td>Workgroup Reports, pt 1</td>
</tr>
<tr>
<td>Oct. 10</td>
<td>Workgroup Reports, pt 2</td>
</tr>
<tr>
<td>Oct. 17</td>
<td>Symposium Week! Final Logistics</td>
</tr>
<tr>
<td>Oct. 24</td>
<td>Welcome to OHDSI</td>
</tr>
</tbody>
</table>
Sept 26: Recent OHDSI Publications

Enabling data sharing and utilization for African population health data using OHDSI tools with an OMOP-common data model (Frontiers in Public Health)

Sylvia Kiwuwa-Muyingo, Biostatistician, African Population and Health Research Center

Characteristics and treatment pathways in pediatric and adult hidradenitis suppurativa: An examination using real world data (JAAD International)

Jill Hardin, Director, Observational Health and Data Analytics, Janssen Research and Development

Ontologizing health systems data at scale: making translational discovery a reality (NPJ Digital Medicine)

Tiffany Callahan, Postdoctoral Researcher, IBM

Learning important common data elements from shared study data: The All of Us program analysis (PLoS One)

Craig Mayer, Applied Clinical Informatics Branch, National Library of Medicine

Padé approximant meets federated learning: A nearly lossless, one-shot algorithm for evidence synthesis in distributed research networks with rare outcomes (Journal of Biomedical Informatics)

Qiong Wu, Research Associate of Biostatistics and Epidemiology, University of Pennsylvania
Three Stages of The Journey

Where Have We Been?
Where Are We Now?
Where Are We Going?
Congratulations to the team of Rowdy de Groot, Daniel Püttmann, Lucas Fleuren, Patrick Thoral, Paul Elbers, Nicolette de Keizer, Ronald Cornet; and the Dutch ICU Data Sharing Against COVID-19 Collaborators on the publication of Determining and assessing characteristics of data element names impacting the performance of annotation using Usagi in the International Journal of Medical Informatics.
OHDSI Shoutouts!

Congratulations to the team of Suehyun Lee, Hyunah Shin, Seon Choe, Min-Gyu Kang, Sae-Hoon Kim, Dong Yoon Kang, and Ju Han Kim on the publication of MetaLAB-HOI: Template standardization of health outcomes enable massive and accurate detection of adverse drug reactions from electronic health records in *Pharmacoepidemiology & Drug Safety*.

**Abstract**

**Purpose**

This study aimed to advance the MetaLAB algorithm and verify its performance with multicenter data to effectively detect major adverse drug reactions (ADRs), including drug-induced liver injury.

**Methods**

Based on MetaLAB, we created an optimal scenario for detecting ADRs by considering demographic and clinical records. MetaLAB-HOI was developed to identify ADR signals using common model-based multicenter electronic health record (EHR) data from the clinical health outcomes of interest (HOI) template and design for drug-exposed and nonexposed groups. In this study, we calculated the odds ratio of 101 drugs for HOI in Konkuk University Hospital, Seoul National University Hospital, Chungbuk National University Hospital, and Seoul National University Bundang Hospital.
OHDSI Shoutouts!

Congratulations to the team of Berta Raventós, Sergio Fernández-Bertolín, María Aragón, Erica Voss, Clair Blacketer, Leonardo Méndez-Boo, Martina Recalde, Elena Roel, Andrea Pistillo, Carlen Reyes, Sebastiáan van Sandijk, Lars Halvorsen, Peter Rijnbeek, Edward Burn, and Talita Duarte-Salles on the publication of Transforming the Information System for Research in Primary Care (SIDIAP) in Catalonia to the OMOP Common Data Model and Its Use for COVID-19 Research in Clinical Epidemiology.

Clinical Epidemiology

Transforming the Information System for Research in Primary Care (SIDIAP) in Catalonia to the OMOP Common Data Model and Its Use for COVID-19 Research

Berta Raventós1,2,*, Sergio Fernández-Bertolín1,*, María Aragón1, Erica A Voss3,*, Clair Blacketer3,*, Leonardo Méndez-Boo5, Martina Recalde1, Elena Roel1,*, Andrea Pistillo1,*, Carlen Reyes1, Sebastiáan van Sandijk8, Lars Halvorsen5, Peter R Rijnbeek1,*, Edward Burn1,6,*, Talita Duarte-Salles1

1Fundación Instituts Universitaris per a la recerca a l’Atenció Primària de Salut Jordi Gol i Gilvars (IDIMPAS), Barcelona, Spain. 2Universitat Autònoma de Barcelona, Bellaterra (Barcelona, Spain), Barcelona, Spain. 3Tessera Pharmaceutical Research and Development, Taunton, MA, USA. 4Department of Medical Informatics, Erasmus University Medical Center, Rotterdam, the Netherlands. 5OHDSI Collaborators, Observational Health Data Sciences and Informatics (OHDSI), New York, NY, USA. 6Instituto de Investigaciones del Servicio de Atención Primaria (IISAP), Instituto Carlos de la Salud, Barcelona, Spain. 7Universidade da Ponte de Lima, Braga, Portugal. 8CIBERenfermedades Respiratorias (CIBERES) Health Research Network, Carlos III Institute, Madrid, Spain. 9Centre for Statistics in Medicine, University of Oxford, Oxford, UK.

*These authors contributed equally to this work.

Correspondence: Talita Duarte-Salles, Fundación Instituts Universitaris per a la recerca a l’Atenció Primària de Salut Jordi Gol i Gilvars (IDIMPAS), Gran Via l’Hospitalet, 587, Barcelona 08010, Spain. Tel: +34913833142. Email: rdumas@ohdsi.org

Purpose: The primary aim of this work was to convert the Information System for Research in Primary Care (SIDIAP) in Catalonia, Spain, to the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM). Our second aim was to provide a descriptive analysis of COVID-19-related outcomes among the general population.

Patients and Methods: We mapped patient-level data from SIDIAP to the OMOP CDM and we performed more than 3,400 data quality checks to assess its readiness for research. We established a general population cohort as of the 1st March 2020 and identified incident COVID-19 diagnoses or test positive for, hospitalised with, admitted to intensive care units (ICU) with, died with, or vaccinated against COVID-19 up to 30th June 2022.

Results: After verifying the high quality of the transformed dataset, we included 5,870,774 individuals in the general population cohort. Of these, 649,472 had either an outpatient COVID-19 diagnosis or positive test result, 55,091 had a hospitalisation, 5,642 had an ICU admission, and 11,233 died with COVID-19. A total of 4,594,515 received a COVID-19 vaccine. People who were hospitalised or died some more commonly older, male, and with more comorbidities. Those admitted to ICU with COVID-19 were generally younger and more often male than those hospitalised and those who died.

Conclusion: We successfully transformed SIDIAP to the OMOP CDM. From this dataset, a general population cohort of 5.9 million individuals was identified and their COVID-19-related outcomes over time were described. The transformed SIDIAP database is a valuable resource that can enable distributed network research in COVID-19 and beyond.

Keywords: electronic health records, medical ontologies, secondary data use, common data model, OMOP
Roadmap and improvement of OHDSI Vocabularies

Alexander Davydov, Christian Reich, Anna Ostropolets

BACKGROUND
The number of requests for new content and issues with existing OHDSI vocabularies continues to increase. This necessitates systematic improvement of the methods and reflection on how we do things. This poster describes three elements of the improvement initiative: landscape assessment of needs, Vocabulary Committee and Roadmap.

METHODS
Landscape assessment
As part of a process improvement initiative, we first assessed community needs. We distributed a two-part survey (general survey and a database-specific survey) through various channels across the community. The survey contained questions about the use of the vocabularies in data and reports, their completeness, correctness, staleness of use, frequency and versioning, frequency of data and vocabularies references, and documentation.

Vocabulary Committee and Roadmap
The report was made open for community feedback in March 2023, published 7 Figure 1) and was used to inform decisions on the roadmap and process improvement activities. The plan was created together with a newly formed Vocabulary Committee that meets on regular basis, oversees and prioritizes the efforts. The committee represents OHDSI and Columbia Coordinating Center George Hrycak, Patrick Ryan, Peter Rydholm, Rae W. Wang, Paul Stein, Max VanZandr and Christian Reich.

Figure 1. First page of 19-page landscape assessment report publicly available in OHDSI Team.

Expect in the upcoming Vocabularies releases:

- Semi-annual releases
- Condition domain overhauled in 2023
- More detail in each release
- Inclusion of content contributed by the community

Figure 2. Roadmap overview

While more details can be found on GitHub. Table 1 shows details for the next release in August.

Table 1: Content of August 2023 release

<table>
<thead>
<tr>
<th>Vocabulary</th>
<th>Version and content</th>
<th>Date</th>
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<tbody>
<tr>
<td>CPFR</td>
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<tr>
<td>LSC</td>
<td>release (year)</td>
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<tr>
<td>NDC, QDL, RIM, and Related Vocabulary Tools</td>
<td>release (year)</td>
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<td>SNOMED</td>
<td>release (year)</td>
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<td>ONTOLOGY</td>
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<td>EMTS</td>
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<tr>
<td>Source (version)</td>
<td>release (year)</td>
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<tr>
<td>Vocabulary Quality Standards (part 1)</td>
<td>release (year)</td>
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<tr>
<td>Vocabulary Quality Standards (part 2)</td>
<td>release (year)</td>
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</tbody>
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Christian Reich, Alexander Davydov, Anna Ostropolets
OMOP for oncology data: a single-centre and network perspective

(Stelios Theophanous, Kieran Zucker, Louise Hick, Edward Bolton, Majid Riaz, Hayley Fenton, John Corkett, Sue Cheeseman, Geoff Hall)

Real-world data, OMOP, plus federated analysis – a new standard for multi-centre, multi-national studies in cancer? A UK NHS perspective

OMOP for oncology data: a single-centre and network perspective

**Background:** Leeds Teaching Hospitals NHS Trust (LTHFT) in the North of England is participating in the Digital Oncology Network for Europe (DigiONE), a European real-world evidence network that aims to establish an international digital infrastructure for oncology care management and research. LTHFT aims to contribute to and benefit from the expertise present across the network to transform cancer-specific data to the OMOP common data model.

**Methods & Results**

1. **Data extraction**
   - LTHFT uses an in-house developed Electronic Health Record (EHR) system called PPM+ to collect diverse and robust data for all cancer patients.
   - Ensures healthcare data conforms to the PMI Coding Principles.

2. **Data extraction from EHR**
   - Currently, data extraction is carried out manually.
   - The capability of EHR platforms will be assessed, in order to automate the extraction of data from unstructured text-data sources.

3. **LTHFT EDEN OMOP project**
   - LTHFT was awarded funding from the European Health Data Ecosystem (EDEN) to support the adoption of the OMOP CDM.
   - We will standardise a subset of patient data to the OMOP CDM v3.3 and will extend this to include genomics healthcare data on all patients.
   - This will facilitate the implementation and adoption of OMOP for cancer data that will be collected and analysed.

4. **OMOP for DigiONE**
   - DigiONE has achieved consensus on the core cancer concepts that will be standardised to the OMOP CDM in all participating hospitals.
   - MEDIC: a minimal cancer dataset, consists of 19 clinically important concepts that accurately describe cancer, enabling outcome research.
   - LTHFT will collect MEDIC data for all cancer patients diagnosed and treated in Leeds. This data will be converted to the OMOP CDM v3.3.

5. **Federated data analysis**
   - Federated data analyses will be implemented on OMOP data using Vantage to draw insights across the DigiONE network.
   - This approach eliminates the need for LTHFT to release highly detailed patient-level data to the DigiONE partners, enhancing data privacy.

Stelios Theophanous, Kieran Zucker, Louise Hick, Edward Bolton, Majid Riaz, Hayley Fenton, John Corkett, Sue Cheeseman, Geoff Hall
Evaluation of treatment effect heterogeneity in the LEGEND-Hypertension study

(Alexandros Rekkas, David van Klaveren, Jenna M. Reps, Peter R. Rijnbeek)

Overall treatment effect estimates derived from the LEGEND-Hypertension study can be supplemented with risk stratified analyses

Title: Evaluation of treatment effect heterogeneity in the LEGEND-Hypertension study.

Background: The LEGEND-Hypertension study generated overall effect estimates for all drug classes used in the treatment of hypertension. We supplement these results with evaluation of treatment effect heterogeneity using a new risk-based framework.

Result 1: Results within strata of predicted acute MI risk on the absolute scale in CCAE.

Result 2: Results within strata of predicted acute MI risk on the relative scale in MOCD.

Methods

Prediction: We stratify the population on their baseline acute MI risk. We develop prediction models for each database and treatment-comparator pair separately using LASSO logistic regression based on a large pre-defined set of baseline covariates.

Estimation: We stratify patients into three risk groups (acute MI risk below 1%, between 1% and 1.5%, and above 1.5%). We use Cox regression to estimate relative effects. We derive absolute risk differences from the differences between the Kaplan-Meier curves on day 130 from treatment initiation.
The use of contraception in females with underlying conditions

(Emma Lippens, Victor Pera, Peter R. Rijnbeek, Katia M.C. Verhamme)

In conclusion, the choice of contraceptive method depends on age and even more on comorbidity.
IncidencePrevalence: An R package to calculate population-level incidence and prevalence rates using the OMOP Common Data Model

(Martí Català, Berta Raventós, Mike Du, Yuchen Guo, Adam Black, Ger Inberg, Xintong Li, Kim López-Güell, Danielle Newby, Maria de Ridder, Cesar Barboza, Talita Duarte-Salles, Katia Verhamme, Peter Rijnbeek, Daniel Prieto Alhambra, Edward Burn)
OHDSI Shoutouts!

Any shoutouts from the community? Please share and help promote and celebrate OHDSI work!

Do you have anything you want to share? Please send to sachson@ohdsi.org so we can highlight during this call and on our social channels. Let’s work together to promote the collaborative work happening in OHDSI!
Three Stages of The Journey

Where Have We Been?
Where Are We Now?
Where Are We Going?
## Upcoming Workgroup Calls

<table>
<thead>
<tr>
<th>Date</th>
<th>Time (ET)</th>
<th>Meeting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuesday</td>
<td>12 pm</td>
<td>Common Data Model Vocabulary Subgroup</td>
</tr>
<tr>
<td>Wednesday</td>
<td>10 am</td>
<td>Perinatal &amp; Reproductive Health</td>
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<tr>
<td>Wednesday</td>
<td>12 pm</td>
<td>Health Equity Journal Club</td>
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<tr>
<td>Wednesday</td>
<td>7 pm</td>
<td>Medical Imaging</td>
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<tr>
<td>Thursday</td>
<td>9 am</td>
<td>OMOP CDM Oncology Vocabulary/Development Subgroup</td>
</tr>
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<td>Thursday</td>
<td>9:30 am</td>
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<td>Thursday</td>
<td>12 pm</td>
<td>HADES</td>
</tr>
<tr>
<td>Thursday</td>
<td>7 pm</td>
<td>Dentistry</td>
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<tr>
<td>Friday</td>
<td>9 am</td>
<td>Phenotype Development &amp; Evaluation</td>
</tr>
<tr>
<td>Friday</td>
<td>9 am</td>
<td>GIS – Geographic Information System General</td>
</tr>
<tr>
<td>Friday</td>
<td>11 am</td>
<td>Clinical Trials</td>
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<tr>
<td>Friday</td>
<td>11:30 am</td>
<td>Steering Group</td>
</tr>
<tr>
<td>Monday</td>
<td>10 am</td>
<td>Healthcare Systems Interest Group</td>
</tr>
<tr>
<td>Monday</td>
<td>4 pm</td>
<td>Eyecare &amp; Vision Research</td>
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<tr>
<td>Monday</td>
<td>6 pm</td>
<td>OMOP &amp; FHIR</td>
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<tr>
<td>Tuesday</td>
<td>9 am</td>
<td>OMOP CDM Oncology Vocabulary/Development Subgroup</td>
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<td>Tuesday</td>
<td>10 am</td>
<td>Registry</td>
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</table>
Identification of cardiotoxicity related to non-small cell lung cancer (NSCLC) treatments

Stefanie Ho Yi Chan
Supervised by Professor Sam Salek, Professor Deborah Layton and Dr Sherael Webley


Introduction

**Cardio-oncology** is a field that focuses on the cardiovascular diseases in cancer patients and work on the prevention, diagnosis and treatment of cardiotoxicity brought by oncology drugs or radiotherapy.

Rapid development in cancer therapies and improved detection strategies

→ death rates caused by cancer decreased

Cardiovascular disease

→ 2nd leading cause of long-term morbidity and fatality among cancer survivors
Aim and objectives

**Aim:** To investigate how different classes of NSCLC drugs demonstrate different cardiotoxicity potentials.

**Primary Objective**
- Describe the frequencies of cardiotoxicity-related outcomes of interest within first 6 months following diagnosis index date in patients diagnosed with NSCLC.

**Secondary Objectives**
- Clinical characteristics of the overall cohort of patients.
- Treatment / Drug utilisation patterns.
- Association between first treatment patterns.

**Exploratory Objectives**
- Associated healthcare cost (including hospital utilisation and drug prescription costs) from diagnosis date through till the end of follow-up period.
Timeline

<table>
<thead>
<tr>
<th>September 2023</th>
<th>October 2023</th>
<th>November 2023</th>
<th>December 2023</th>
<th>Q1 2024</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Collection / Extraction</td>
<td>Data Collection / Extraction</td>
<td>Data Analysis</td>
<td>Write-Up</td>
<td>Dissemination</td>
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<td>Data Analysis</td>
<td>Write-Up</td>
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</tbody>
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Q1 2024 Dissemination
Next steps ...

- Database / data partners required
  (does not necessarily need to be in the UK)
- Ideally be able to access the data by mid-October
Thank you!

Stefanie Ho Yi Chan
PhD Researcher
University of Hertfordshire, UK
h.chan7@herts.ac.uk / stefanie.chanhy@gmail.com
Global Symposium

Oct. 20-22 • East Brunswick, NJ, USA
Hilton East Brunswick Hotel & Executive Meeting Center

bit.ly/OHDSI2023Registration
Global Symposium

Common Data Model / Network Data Quality: -- Global Symposium Meeting

When: Saturday, October 21, 8:00am-12:00pm EST

The Common Data Model and Network Data Quality working groups will host an in-person meeting at the 2023 OHDSI Global Symposium on October 21, 2023, from 8:00am - 12:00pm.

Common Data Model/Network Data Quality: in this session we will discuss the OHDSI Data Network, including goals, incentives, and plans for the future. We would like to hear from current and potential data partners about the barriers they face to joining and how we as a community can work together to overcome them. We will also highlight potential network studies end give growth opportunities.

You should join this session if you:
- Are a collaborator currently participating in the OHDSI Data Network, meaning you shared a Database Profile with the OHDSI Coordinating Center.
- Are a data owner who would like to participate in a network study.
- Are a data vendor looking to market their data to potential customers.
- Are a researcher looking for databases with particular attributes.
- Are interested in the OHDSI Data Network and want to contribute to the planning and discussion.

Agenda:

Time | Topic
--- | ---
8:00 - 8:15 | OHDSI: Where have we been? Where are we going? George Hripcsak, Columbia Univ.

Community Highlights:
- OMOP CDM users and the OHDSI data network Clair Blacketer, Johnson & Johnson
- OHDSI standardized vocabularies Alexander Deyoviy, Odysseya Data Services
- OHDSI open-source community Kat Sadowi, Boehringer Ingelheim
- OHDSI Europe 2024 Peter Rijnbeek, Erasmus MC
- OHDSI Asia-Pacific 2024 Mengling Feng, National Univ. of Singapore

Observational Data Standards & Management (Posters)

2 FinDOP - a population-based data network

3 From OMOP to CHDC: SDM, Successes, Challenges, and Future Opportunities of using EHR Data for Drug Repurposing in COVID-19

4 Augmenting the National COVID Cohort Collaborative (N3C) Dataset with Medicare and Medicaid (CMS) Data: Secure and Deidentified Clinical Dataset

Health Analytics: Early to Evidence Suite OHDSI Hackathon

When: Saturday, October 21, 8:00am-12:00pm and Sunday, October 22, 1:00pm-5:00pm EST

During the OHDSI Hackathon, participants will work on the HADES codebase with support from several HADES maintainers. Participants can work in groups, and we welcome both new and experienced contributors to join. Part 1 takes place Saturday morning and Part 2 takes place Sunday afternoon.

Target audience: Developers interested in working on the HADES codebase. Some experience in R is recommended.

-presenters:
- Patrick Ryan, Johnson & Johnson, Columbia Univ.
- Anna Astropotails, Odysseya Data Services
- Martijn Schuinem, Johnson & Johnson, Univ. of California-Los Angeles

Health Analytics: Early to Evidence Suite OHDSI Hackathon

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Presenters:
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- Anna Astropotails, Odysseya Data Services
- Martijn Schuinem, Johnson & Johnson, Univ. of California-Los Angeles

Employees will be available throughout the day.

bit.ly/OHDSI2023-Agenda
OHDSI HADES releases: ResultModelManager 0.5.1

ResultModelManager

Introduction

RMM is an R package designed to handle common ohdsi results data management functions by providing a common API for data model migrations and definitions.

System Requirements

Requires R. Some of the packages used by ResultModelManager require Java.

Installation

1. See the instructions here for configuring your R environment, including Java.
2. In R, use the following commands to download and install ResultModelManager:
Openings at Boehringer Ingelheim

Director, Real World Data & Analytics - Data Domain Owner
Apply Now

Real World Evidence Data Engineer
Apply Now
Opening: Postdoctoral Associate/Data Analyst

Job Description:
We are seeking a talented and dedicated Postdoctoral Associate/Data Analyst to join our dynamic team. In this role, you will play a pivotal part in advancing our mission of improving health outcomes through data-driven research. You will have the opportunity to work with diverse healthcare datasets, develop innovative analytical methods, and collaborate with experts in the field.

The Postdoctoral Associate/Data Analyst should possess significant experience in R and Rstudio, with specific expertise in database management using PostgreSQL—critical requirements within the OHDSI network. Your responsibilities will include assisting the Principal Investigator (Dr. Yuan Lu from Yale University) and Co-investigator (Drs. Marc Suchard from UCLA) in creating the analytic tool stack and performing related analyses.

Key Responsibilities:
- Collaborate with multidisciplinary teams to design and execute data analysis projects.
- Develop and implement statistical and machine learning models for healthcare data.
- Perform data extraction and preprocessing tasks to prepare datasets for analysis.
- Conduct exploratory data analysis and visualization to extract insights from healthcare data.
- Assist in the development and maintenance of OHDSI’s open-source tools and resources.
- Communicate findings and insights through reports, presentations, and publications.
- Stay up-to-date with the latest advancements in data science and healthcare informatics.

Email: y.lu@yale.edu
Where Are We Going?

Any other announcements of upcoming work, events, deadlines, etc?
Three Stages of The Journey

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Sept. 19 • OHDSI Journal Club: 11th Revision of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology

Catherine Cohet
Pharmacoepidemiology Senior Specialist, RWE Workstream, Data Analytics & Methods Task Force, European Medicines Agency

Xintong Li
DPhil student in Medical Statistics and Clinical Epidemiology, University of Oxford

Kim López Güell
DPhil student in Medical Statistics and Clinical Epidemiology, University of Oxford

Daniel Morales
Senior Pharmacoepidemiologist, European Medicines Agency

Niklas Norén
Chief Science Officer, Uppsala Centre

Luis Pinheiro
Senior Epidemiology Expert, European Medicines Agency

Albert Prats-Uribe
Senior Clinical Researcher and Public Health Specialist, University of Oxford

Dani Prieto-Alhambra
Section Head - Health Data Sciences, Botnar Research Centre and Professor, University of Oxford and Erasmus MC