CDM/ DQD Workgroup Updates + Phenotype Phebruary Report

OHDSI Community Call
Feb. 15, 2022 • 11 am ET
<table>
<thead>
<tr>
<th>Date</th>
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## Future OHDSI Community Calls

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February 22 OHDSI Community Call

ATLAS/Web API Workgroup Update
Anthony Sena

Medical Imaging Workgroup Update
Paul Nagy

Phenotype Phebruary Update #3
Patrick Ryan
Three Stages of The Journey

Where Have We Been?
Where Are We Now?
Where Are We Going?
Erasmus Awarded DARWIN EU Contract

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

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

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

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

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

Real-world healthcare data

Erasmus MC contracted to establish DARWIN EU® Coordination Centre for the European Medicines Agency

The Erasmus MC will work closely with the European Medicines Agency on the establishment of the Coordination Centre for the Data Analysis and Real World Interrogation Network (DARWIN EU®).

https://www.ohdsi.org/ohdsi-news-updates
Phenotype Phebruary Daily Updates

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

This page will provide direct links to each forum post, which is where conversations around each specific phenotype should be held.

Please be active in these discussions. What ways can you contribute?

1. Join the conversation
   - Discussions will be here on forums.ohdsi.org
   - Each day will be a new thread
     - Ex: Look for: "Phenotype Phebruary Day 1 – Type 2 diabetes mellitus"
   - Explore the definitions and review the results provided
   - Reply with your thoughts, reflections, insights and question

2. Evaluate the cohort definitions in your data
   - Execute cohort definitions and CohortDiagnostics in your CDM
   - Share insights you learn from your data on the forums
   - Share results to compile across the network on data.ohdsi.org

3. Lead a discussion
   - Patrick will be leading the discussion for the first 7 days, but if others would like to similarly lead a phenotype development and evaluation activity, contact ryan@ohdsi.org or chat with him in OHDSI MSTeams, tell me your desired phenotype target and calendar date you want to commit to.

https://www.ohdsi.org/phenotype-phebruary

Daily Phenotype February Links

Feb. 1 • Type 2 Diabetes Mellitus
Feb. 2 • Type 1 Diabetes Mellitus
Feb. 3 • Atrial Fibrillation
Feb. 4 • Multiple Myeloma
Feb. 5 • Alzheimer’s Disease
Feb. 6 • Hemorrhagic Events
Feb. 7 • Neutropenia
Feb. 8 • Kidney Stones
Feb. 9 • Delirium
Feb. 10 • Systemic Lupus Erythematosus
Feb. 11 • Suicide Attempts
Feb. 12 • Parkinson’s Disease and Parkinsonism
Feb. 13 • Attention Deficit Hyperactivity Disorder
Feb. 14 • Hypertension
Feb. 15 • Acute Myocardial Infarction
Feb. 16 •
Feb. 17 •
Feb. 18 •
Feb. 19 •
Feb. 20 •
Feb. 21 •
Feb. 22 •
Feb. 23 •
Feb. 24 •
Feb. 25 •
Feb. 26 •
Feb. 27 •
Feb. 28 •
OHDSI Shoutouts!

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

Have a study published? Please send to sachson@ohdsi.org so we can share 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

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<thead>
<tr>
<th>Date</th>
<th>Time (ET)</th>
<th>Meeting</th>
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<tbody>
<tr>
<td>Tuesday</td>
<td>1 pm</td>
<td>Common Data Model</td>
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<tr>
<td>Wednesday</td>
<td>9 am</td>
<td>FHIR and OMOP Data Model Harmonization Subgroup (Zoom)</td>
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<tr>
<td>Wednesday</td>
<td>9 am</td>
<td>Africa Chapter</td>
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<tr>
<td>Wednesday</td>
<td>10 am</td>
<td>FHIR and OMOP Digital Quality Measurements Subgroup (Zoom)</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>Thursday</td>
<td>8 am</td>
<td>Psychiatry</td>
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<td>Thursday</td>
<td>12 pm</td>
<td>HADES</td>
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<tr>
<td>Thursday</td>
<td>12 pm</td>
<td>FHIR and OMOP Oncology Subgroup</td>
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<td>Thursday</td>
<td>6 pm</td>
<td>FHIR and OMOP Terminologies Subgroup (Zoom)</td>
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<tr>
<td>Friday</td>
<td>10 am</td>
<td>Vaccine Vocabulary</td>
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<tr>
<td>Friday</td>
<td>10:30 am</td>
<td>Clinical Trials</td>
</tr>
<tr>
<td>Monday</td>
<td>10 am</td>
<td>GIS-Geographical Information System</td>
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</table>

[www.ohdsi.org/upcoming-working-group-calls](www.ohdsi.org/upcoming-working-group-calls)
Get Access To Different Teams/WGs/Chapters

Welcome to OHDSI!

The Observational Health Data Sciences and Informatics (OHDSI) program is a multi-stakeholder, interdisciplinary collaborative to bring out the value of health data through large-scale analytics. All our solutions are open-source.

OHDSI has established an international network of researchers and observational health databases with a central coordinating center located at Duke University.

2021 OHDSI Symposium

The 2021 OHDSI Global Symposium featured plenary presentations on OHDSI's Impact on the COVID-19 Pandemic, as well as on the Journey to Reliable Evidence. The main days included the State of the Community Presentation, the Collaborator Showcase, and a memorable Closing Ceremony that focused on OHDSI’s work through the perspective of a patient.

There were also a pair of full-day activities, including the 2021 OHDSI Panel.

5. Select the workgroups you want to join (you can refer to the WIKI for work group objectives)

- ATLAS
- Clinical Trials
- Common Data Model
- Data Quality Dashboard Development
- Early-stage Researchers
- Education Work Group
- FHIRE and OMOP
- Geographic Information System (GIS)
- HADES Health Analytics Data-to-Evidence Suite
- Healthcare Systems Interest Group (formerly EHR)
- Health Equity
- Latin America
- Medical Devices
- Medical Imaging
- Natural Language Processing
- OHDSI APAC
- OHDSI APAC Steering Committee
- OHDSI Steering Committee
- Oncology
- Open-source Community
- Phenotype Development and Evaluation
- Population-Level Effect Estimation / Patient-Level Prediction
- Psychiatry
- Registry (formerly UK Biobank)
- Surgery and Perioperative Medicine
- Vaccine Evidence
- Vaccine Vocabulary

6. Select the chapter(s) you want to join

- Africa
- Australia
- China
- Europe
- Japan
- Korea
- Singapore
- Taiwan

7. Select the studies you want to join

- HEMA-Health Equity Research Assessment
- PIONEER for Prostate Cancer (study-a-then-ended)
- SCYLLA (SARS-Cov-2 Large-scale Longitudinal Analysis)

@OHDSI
www.ohdsi.org
#JoinTheJourney
Get Access To Different Teams/WGs/Chapters

Get Access To Different Teams/WGs/Chapters

Join Work groups, Chapters, and Studies Registration

OHDSI is using MSTeams to further encourage active collaboration within the community. Within the OHDSI organization, there are separate teams for work groups, chapters, and studies, as well as OHDSI community activities (such as the OHDSI2020 Symposium). All teams are open to all collaborators. Below please indicate which Team you would like to join and the OHDSI coordinating center team will grant access.

1. First and Last Name *

Enter your answer

5. Select the workgroups you want to join (you can refer to the WIKI for work group objectives)

- ATLAS
- Clinical Trials
- Common Data Model
- Data Quality Dashboard Development
- Early-stage Researchers
- Education Work Group
- EHR and OMOP
- Geographic Information System (GIS)
- HADES Health Analytics Data-to-Evidence Suite
- Healthcare Systems Interest Group (formerly EHR)
- Health Equity
- Latin America
- Medical Devices
- Medical Imaging
- Natural Language Processing
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- Phenotype Development and Evaluation
- Population-Level Effect Estimation / Patient-Level Prediction

6. Select the chapter(s) you want to join

- Africa
- Australia
- China
- Europe
- Japan
- Korea
- Singapore
- Taiwan

7. Select the studies you want to join

- HERR-High Equity Researcher Assessment
- PIONEER for Prostate Cancer (study-a-thon ended)
- SCYLLA (SARS-CoV-2 Large-scale Longitudinal Analysis)
Next CBER Best Seminar

Speaker: Dr. Nicole Pratt
Professor, University of South Australia

Description: As recently approved COVID-19 vaccines are rolled out globally, safety signals will be identified from spontaneous reports and other data sources. Although some work has been done to assess the validity of methods for vaccine safety surveillance, discussion remains on the best way to perform analyses in real-world data to ensure rigorous and rapid identification of safety signals. In this talk, we will discuss the “Evaluating Use of Methods for Adverse Event Under Surveillance (for vaccines) (EUMEAUS)” task force and its findings on the comparative performance of different analytical methods for the assessment of comparative vaccine safety. We will discuss our findings to-date describing our evaluation of different surveillance methods (historic rate, cohort, self-controlled, etc).

Feb 23, 2022 11:00 AM in Eastern Time (US and Canada)

Speakers

Dr. Nicole Pratt
Deputy Director of the Quality Use of Medicines and Pharmacy Research Centre @University of South Australia

Dr. Nicole Pratt is the Deputy Director of the Quality Use of Medicines and Pharmacy Research Centre, University of South Australia. She is a member of the Drug Utilisation Subcommittee (DUSC) of the Australian Department of Health Pharmaceutical Benefits Advisory Committee (PBAC). She has a particular interest in new statistical methodologies to study the effectiveness and safety of medicine use and in the development of tools for post-marketing surveillance of medicines. Nicole leads the evaluation of the Department of Veterans Affairs, Veterans’ Medicines Advice and Therapeutics Education Service (Veterans’ MATES) program which uses administrative claims data to develop and evaluate interventions to improve use of medicines in the veteran population in Australia. She was a chief investigator of an NHMRC Centre of Research Excellence in post-market surveillance of medicines and medical devices.
Scaling OHDSI open-source community projects, lessons learned by Oncology Workgroup

Authors: Shilpa Ratwani, Asieh Golozar, Michael Gurley, Andrew Williams, Robert Miller, Christian Reich, Dmitry Dymshyts, Michael Kallfelz, Rimma Belenkaya
CemConnector is an R Package and RESTful API for utilizing the Common Evidence Model for selecting negative controls, enriching studies and exploring relationships between outcomes and exposures.

CemConnector: A RESTful application programming interface and client library for the Common Evidence Model (CEM)
Authors: James P. Gilbert, Erica A. Voss, Christopher A. Knoll, Patrick B. Ryan
#OHDSISocialShowcase This Week

Disease Progression Modeling Workbench 360 [DPM360]

Authors: Parthasarathy Suryanarayanan, Prithwish Chakraborty, Piyush Madan, Nelson Bore, William Ogallo, Rachita Chandra, Mohamed Ghalwash, I. Buleje, Sekou Lionel Remy, Shreyans Sethi, Shilpa Mahatma, P. Meyerr, Jianying Hu

WEDNESDAY
Evaluating Patient Count Vs Hospitalization Risk for Common Clinical Trial Eligibility Criteria: A Case Study for Relapsed/Refractory Lymphoma/Leukemia

Authors: James Rogers, Casey N. Ta, Cong Liu, Ali Soroush, Ying Kuen Cheung, George Hripcsak, Chunhua Weng

**Background**

Clinical trials are essential for generating medical evidence. Within the same disease domain, common eligibility criteria (CEC) patterns can be observed and may be applied for safety reasons and/or reducing study selection heterogeneity. However, the expenses of recruiting available patients who might benefit from participation in a clinical trial can be significant. This study focuses on CECs concerning hospitalization and risk and proposes a methodology for evaluating CECs using different CEC sets to inform potential cost savings. The study was conducted using adult relapsed/refractory (RR) lymphoma leukemia trials as a case study.

**Methods**

**Evaluative Procedure**

<table>
<thead>
<tr>
<th>Data Sources</th>
<th>Details</th>
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<tbody>
<tr>
<td>Real Enrollment</td>
<td>Provides candidate eligibility criteria.</td>
</tr>
<tr>
<td>Simulated Enrollment</td>
<td>Provides patient data from a large academic medical center for cohort construction.</td>
</tr>
</tbody>
</table>

**Evaluative Procedure**

1. **Outcome Measure**: CECs associated with hospitalization risk for each evaluated CEC set.
2. **Procedures**: Identify potential cost savings for each evaluated CEC set.
3. **Evaluative Constructs**: CECs with potential cost savings.

**Results**

Three CECs were found, with no prior malignancy found to be the most restrictive.

**Conclusions**

- Standardized and no prior cancer suggests the lowest hospitalization risk, but at the expense of the selected available number of patients to recruit for study.

- The procedure demonstrates a positive approach for better estimating and addressing the effect of CECs on patient eligibility and enrollment.

- Real samples and CECs data were highly invariant results, so CEC found to have marked effects from this level might not account for future differences on different data sources.
Representation of investigational drugs in the OMOP CDM

Authors: Michael Kallfelz, Dmitry Dymshyts, Meera Patel, Christian Reich, Jeremy Warner, Rimma Belenkaya
Where Are We Going?

Any other announcements of upcoming work, events, deadlines, etc?
Welcome To OHDSI Newcomers

Are there any new people to the OHDSI community call who would like to introduce themselves?

Please raise your hand and share why you are interested in joining the OHDSI community.
Three Stages of The Journey

Where Have We Been?
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February 15 OHDSI Community Call

Common Data Model Workgroup Update
Clair Blacketer

Data Quality Dashboard Workgroup Update
Clair Blacketer

Phenotype Phebruary Update #2
Patrick Ryan