CDM/ DQD Workgroup Updates + Phenotype Phebruary Report

OHDSI Community Call
Feb. 15, 2022 • 11 am ET

Future OHDSI Community Calls

Date	Topic
Feb. 15	Workgroup Updates (Common Data Model, Data Quality), Phenotype Phebruary Report
Feb. 22	Workgroup Updates (ATLAS/WebAPI, Medical Imaging), Phenotype Phebruary Report
Mar. 1	Breakout Sessions (Characterization, Estimation, Prediction)
Mar. 8	CDM Workshop (Part 1)
Mar. 15	CDM Workshop (Part 2)
Mar. 22	OHDSI Vocabulary Journey
Mar. 29	Reproducibility

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Mar. 29	Reproducibility

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

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

Share

News 09/02/2022

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

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

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

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

Real-world healthcare data

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

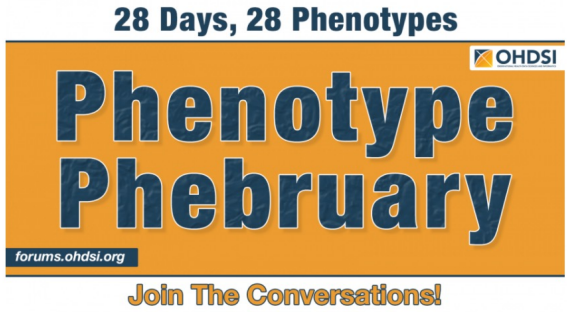
The Erasmus MC will work closely with the European Medicines Agency on the establishment of the Coordination Centre for the Data Analysis and Real World Interrogation Network (DARWIN EU®).

https://www.ohdsi.org/ohdsi-news-updates

Phenotype Phebruary

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

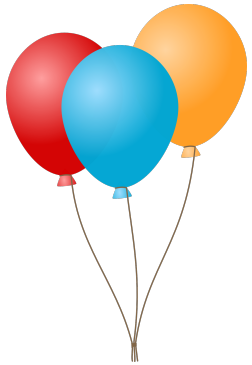
- Patrick will be leading the discussion for the first 7 days, but if others would like to similarly lead a phenotype development and evaluation activity, contact ryan@ohdsi.org or chat with him in OHDSI MSTeams, tell me your desired phenotype target and calendar date you want to commit to.

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 •

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

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

Date	Time (ET)	Meeting
Tuesday	1 pm	Common Data Model
Wednesday	9 am	FHIR and OMOP Data Model Harmonization Subgroup (Zoom)
Wednesday	9 am	Africa Chapter
Wednesday	10 am	FHIR and OMOP Digital Quality Measurements Subgroup (Zoom)
Wednesday	12 pm	Health Equity Journal Club
Thursday	8 am	Psychiatry
Thursday	12 pm	HADES
Thursday	12 pm	FHIR and OMOP Oncology Subgroup
Thursday	6 pm	FHIR and OMOP Terminologies Subgroup (Zoom)
Friday	10 am	Vaccine Vocabulary
Friday	10:30 am	Clinical Trials
Monday	10 am	GIS-Geographical Information System

www.ohdsi.org/upcoming-working-group-calls

Get Access To Different Teams/WGs/Chapters

5. Select the workgroups you want to join (you can refer to the WIKI for work group objectives www.ohdsi.org/web/wiki/doku.php?id=projects:overview)

- [ ] ATLAS
- [ ] Clinical Trials
- [ ] Common Data Model
- [ ] Data Quality Dashboard Development
- [ ] Early-stage Researchers
- [ ] Education Work Group
- [ ] FHIR 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

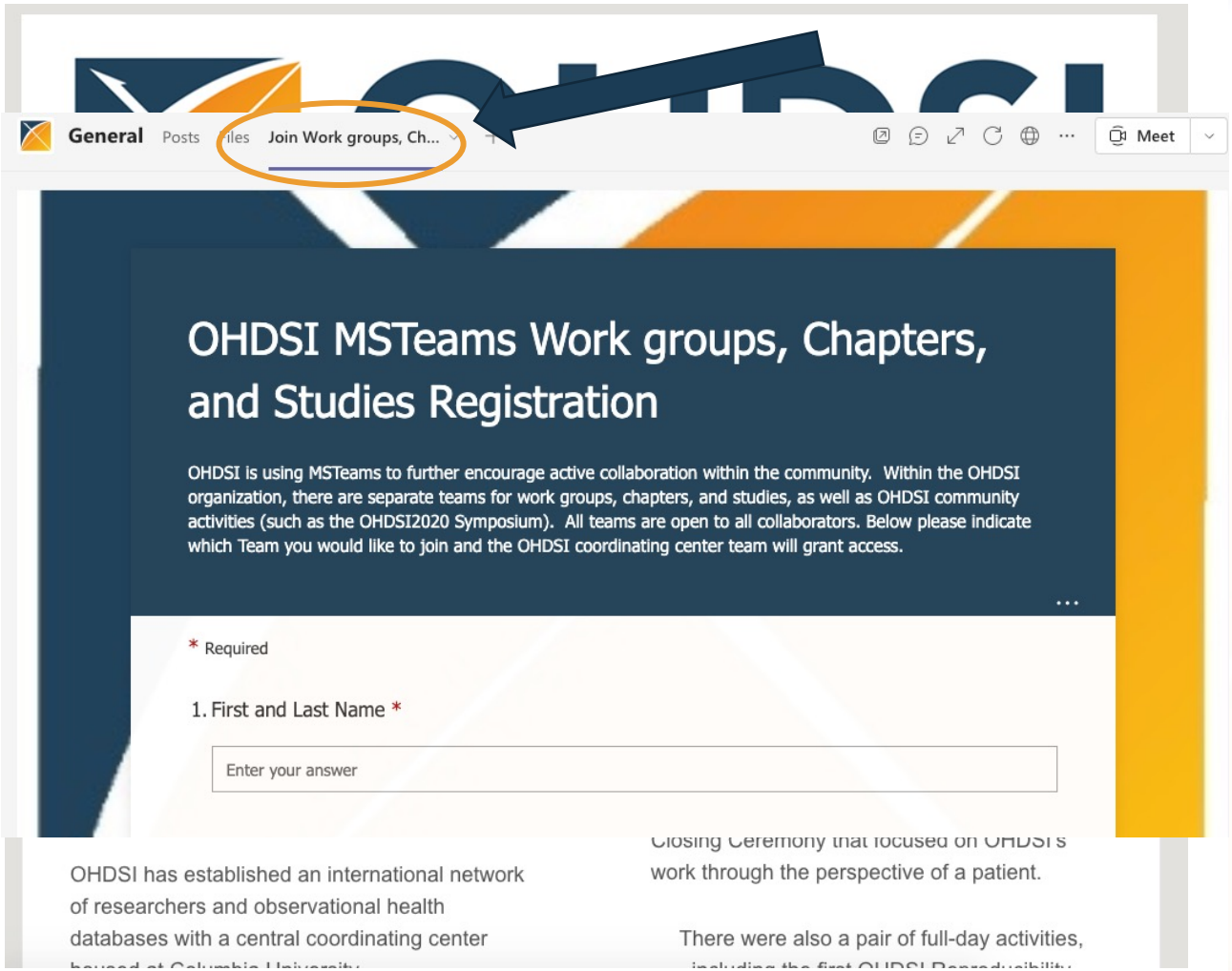
6. Select the chapter(s) you want to join

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

7. Select the studies you want to join

- [ ] HERA-Health Equity Research Assessment
- [ ] PIONEER for Prostate Cancer (study-a-thon ended)
- [ ] SCYLLA (SARS-Cov-2 Large-scale Longitudinal Analyses)

Get Access To Different Teams/WGs/Chapters



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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

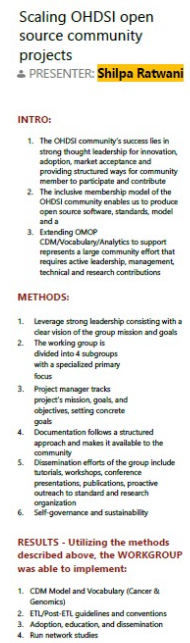
Dr. Nicole Pratt

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 Cenre of Research Excellence in post-market surveillance of medicines and medical devices.

Wed., Feb. 23, 11 am ET

#OHDSISocialShowcase This Week


Scaling OHDSI open source community projects

PRESENTER: Shilpa Ratwani

INTRO:

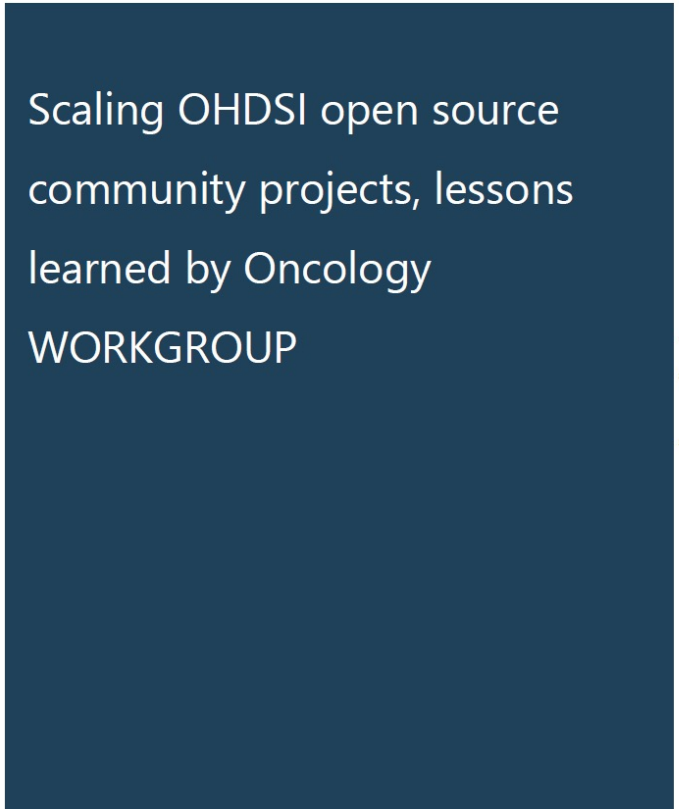
1. The OHDSI community's success lies in strong thought leadership for innovation, adoption, market acceptance and providing structured ways for community member to participate and contribute
2. The inclusive membership model of the OHDSI community enables us to produce open source software, standards, model and a
3. Extending OMOP CDM/Vocabulary/Analytics to support represents a large community effort that requires active leadership, management, technical and research contributions

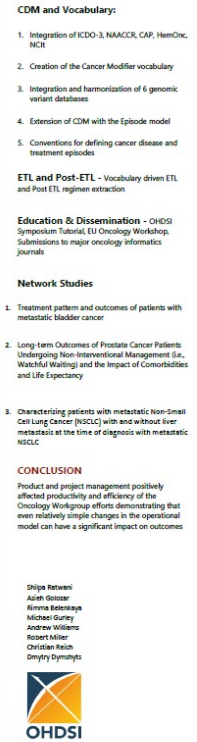
METHODS:

1. Leverage strong leadership consisting with a clear vision of the group mission and goals
2. The working group is divided into 4 subgroups with a specialized primary focus
3. Project manager tracks project's mission, goals, and objectives, setting concrete goals
4. Documentation follows a structured approach and makes it available to the community
5. Dissemination efforts of the group include tutorials, workshops, conference presentations, publications, proactive outreach to standard and research organization
6. Self-governance and sustainability

RESULTS - Utilizing the methods described above, the WORKGROUP was able to implement:

1. CDM Model and Vocabulary (Cancer & Genomics)
2. ETL/Post-ETL guidelines and conventions
3. Adoption, education, and dissemination
4. Run network studies




CDM and Vocabulary:

1. Integration of ICDO-3, NAACCR, CAP, HemOnc, NCIt
2. Creation of the Cancer Modifier vocabulary
3. Integration and harmonization of 6 genomic variant databases
4. Extension of CDM with the Episode model
5. Conventions for defining cancer disease and treatment episodes

ETL and Post-ETL - Vocabulary driven ETL and Post ETL regimen extraction

Education & Dissemination - OHDSI Symposium Tutorial, EU Oncology Workshop, Submissions to major oncology informatics journals

Network Studies

1. Treatment pattern and outcomes of patients with metastatic bladder cancer
2. Long-term Outcomes of Prostate Cancer Patients Undergoing Non-Interventional Management (i.e., Watchful Waiting) and the Impact of Comorbidities and Life Expectancy
3. Characterizing patients with metastatic Non-Small Cell Lung Cancer (NSCLC) with and without liver metastasis at the time of diagnosis with metastatic NSCLC

CONCLUSION

Product and project management positively affected productivity and efficiency of the Oncology Workgroup efforts demonstrating that even relatively simple changes in the operational model can have a significant impact on outcomes

Shilpa Ratwani
Asieh Golozar
Rimma Belenkaya
Michael Gurley
Andrew Williams
Robert Miller
Christian Reich
Dmitry Dymshyts

OHDSI

MONDAY

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

#OHDSISocialShowcase This Week

CemConnector:
A RESTFul application programing interface and client library for the Common Evidence Model (CEM)

PRESENTER: **Jamie** Gilbert

INTRO:
- **The common evidence model is an incredibly useful resource containing information from clinical trials, drug labels, literature and spontaneous reports (1,2).**
- **This is commonly used to assist in the selection of negative control outcomes/exposures, but combines available pharmacovigilance information in a single resource**
- **Currently, access is limited and too few people are taking advantage of this resource.**
- **CemConnector makes it easier to access this repository of information**

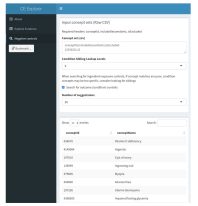
METHODS
1. The code is written in R and is fully open source
2. Uses pre-computed lookup across **OMOP standard vocabulary** to improve performance
3. Queries concept sets can be made with **RXNorm ingredients** or **SNOMED** terms
4. Data can be accessed from **public API** (after requesting a key) or via a database directly

RESULTS
- Negative control outcomes and exposure sets can be generated in a few seconds
- Shiny application provides convenient interface to search controls
- API allows easy integration into other tools
- Controls can now be programmatically selected in population level estimation studies directly

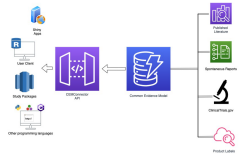
https://github.com/OHDSI/CemConnector

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

Screenshots of Shiny App



System level overview



References

1. Voss EA, *et al.* Accuracy of an automated knowledge base for identifying drug adverse reactions. J Biomed Inform. 2017 Feb 1;66:72–81.

2.Boyce RD, *et al.* Bridging Islands of Information to Establish an Integrated Knowledge Base of Drugs and Health Outcomes of Interest. Drug Saf. 2014;(37):557–567

James P. Gilbert, Erica A. Voss, Christopher A. Knoll, Patrick B. Ryan

janssen PHARMACEUTICAL COMPANIES OF Johnson&Johnson

OHDSI

TUESDAY

CemConnector: A RESTFul application programing 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

WEDNESDAY

Disease Progression Modeling Workbench 360

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

#OHDSISocialShowcase This Week

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

James R. Rogers[1]; Casey N. Ta[1]; Cong Liu[1]; Ali Soroush[1,2]; Ying Kuen Cheung[3]; George Hripcsak[1,4]; Chunhua Weng[1]

[1]Department of Biomedical Informatics, Columbia University, New York, NY, USA; [2]Division of Gastroenterology, Department of Medicine, Columbia University Irving Medical Center, New York, NY, USA; [3]Department of Biostatistics, Columbia University, New York, NY, USA; [4]Medical Informatics Services, New York-Presbyterian Hospital, New York, NY, USA

Background

-Clinical trials remain essential for generating medical evidence

-Within the same disease domain, common eligibility criteria (CEC) patterns can be observed as many of the same criteria might be applied for safety reasons and/or reducing study population heterogeneity, but at the expense of reducing available patients who might benefit from participation

-**Objective:** To assess the tradeoff in patient count vs hospitalization risk when using different CEC sets, by using adult relapsed/refractory (r/r) lymphoma/leukemia trials as a case study

Methods

General Procedure | **Details**

Data Sources

-23 trials available for r/r lymphoma/leukemia

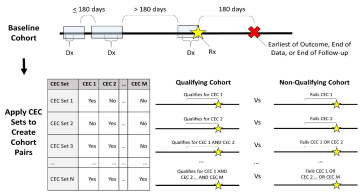
-Provides candidate eligibility criteria

-Provides patient data (from a large academic medical center) for cohort construction

CEC Identification

-Select concepts appearing in at least 25% of all trials
-Remove concepts if too vague or not reasonably captured in EHR
-Manually cross-check concepts to original ClinicalTrials.gov source text

Cohort Construction



-Rx = portion of relevant chemotherapy or corticosteroid
-Dx = lymphoma or leukemia diagnosis
-Outcome = hospitalization (length of stay > 1 day)

Analysis

-Perform power calculations to identify powered CEC sets
-Create scatterplot between CEC patient count and hospitalization risk for each powered CEC set
-Apply k-means clustering to identify CEC patterns

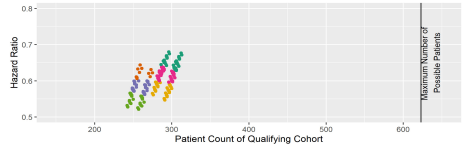
Results

-There were 9 CEC found, with no prior malignancy found to be the most restrictive

CEC Label	CEC Description	Number of Trials N (%)	Patient Count N (%)
Start	N/A	23 (100)	623 (100)
No HIV	No HIV within the past 365 days	20 (86.96)	614 (98.56)
No HBV/HCV	No HBV/HCV within the past 365 days	19 (82.61)	613 (98.39)
Not pregnant	No evidence of current pregnancy within the past 60 days	19 (82.61)	622 (99.84)
No prior chemo/rad	No prior chemotherapy or radiotherapy within the past 14 days (excludes index)	18 (78.26)	590 (94.70)
No prior malignancy	No prior malignancy (beside lymphoma, leukemia, non-melanoma skin cancer, melanoma in situ, carcinoma in situ of the cervix, benign tumor, or lipomatous tumor) within the past 1095 days	17 (73.91)	313 (50.24)
Adequate eGFR	Most recent eGFR measure within the past 180 days > 30 mL/min/1.73m^2 (per MDRD equation)	11 (47.83)	525 (84.27)
No infection	No active infection within the past 30 days	10 (43.48)	604 (96.95)
Adequate ANC	Most recent ANC measure within the past 180 days > 1000/mm3	9 (39.13)	587 (94.22)
No corticosteroid	No prior corticosteroid use within the past 7 days (excludes index)	9 (39.13)	612 (98.23)

-Of 511 possible CEC sets, only 256 (50%) were powered; all included the CEC of no prior malignancy

-Combining no infection and no prior chemo/rad suggests the lowest hospitalization risk, but at the expense of the smallest available number of patients to recruit (i.e. Cluster 5)



	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Cluster 5	Cluster 6
N of CEC Sets	33	22	58	52	48	43
No HIV	8 (24%)	2 (9%)	22 (38%)	22 (42%)	40 (83%)	34 (79%)
No HBV/HCV	12 (36%)	12 (55%)	28 (48%)	25 (48%)	24 (50%)	27 (63%)
Not pregnant	17 (52%)	11 (50%)	29 (50%)	27 (52%)	24 (50%)	20 (47%)
No prior chemo/rad	0 (0%)	0 (0%)	24 (41%)	24 (46%)	40 (83%)	40 (93%)
No prior malignancy	33 (100%)	22 (100%)	58 (100%)	52 (100%)	48 (100%)	43 (100%)
Adequate eGFR	13 (39%)	8 (36%)	24 (41%)	25 (48%)	32 (67%)	26 (60%)
No infection	0 (0%)	22 (100%)	58 (100%)	0 (0%)	48 (100%)	0 (0%)
Adequate ANC	9 (27%)	4 (18%)	28 (48%)	29 (56%)	32 (67%)	26 (60%)
No corticosteroid	13 (39%)	14 (64%)	26 (45%)	32 (62%)	24 (50%)	19 (44%)

Conclusions

-This procedure demonstrates a possible approach for better estimating and addressing the effect of eligibility criteria on patient counts and safety risk

-Trial sample and EHR data can greatly impact results, so CEC found to have muted effects from this analysis might not necessarily hold in other environments or different data sources

Columbia University Irving Medical Center

Contact: jrr2194@cumc.columbia.edu
; Funding: NLM 5T15LM007079, NLM R01LM009886

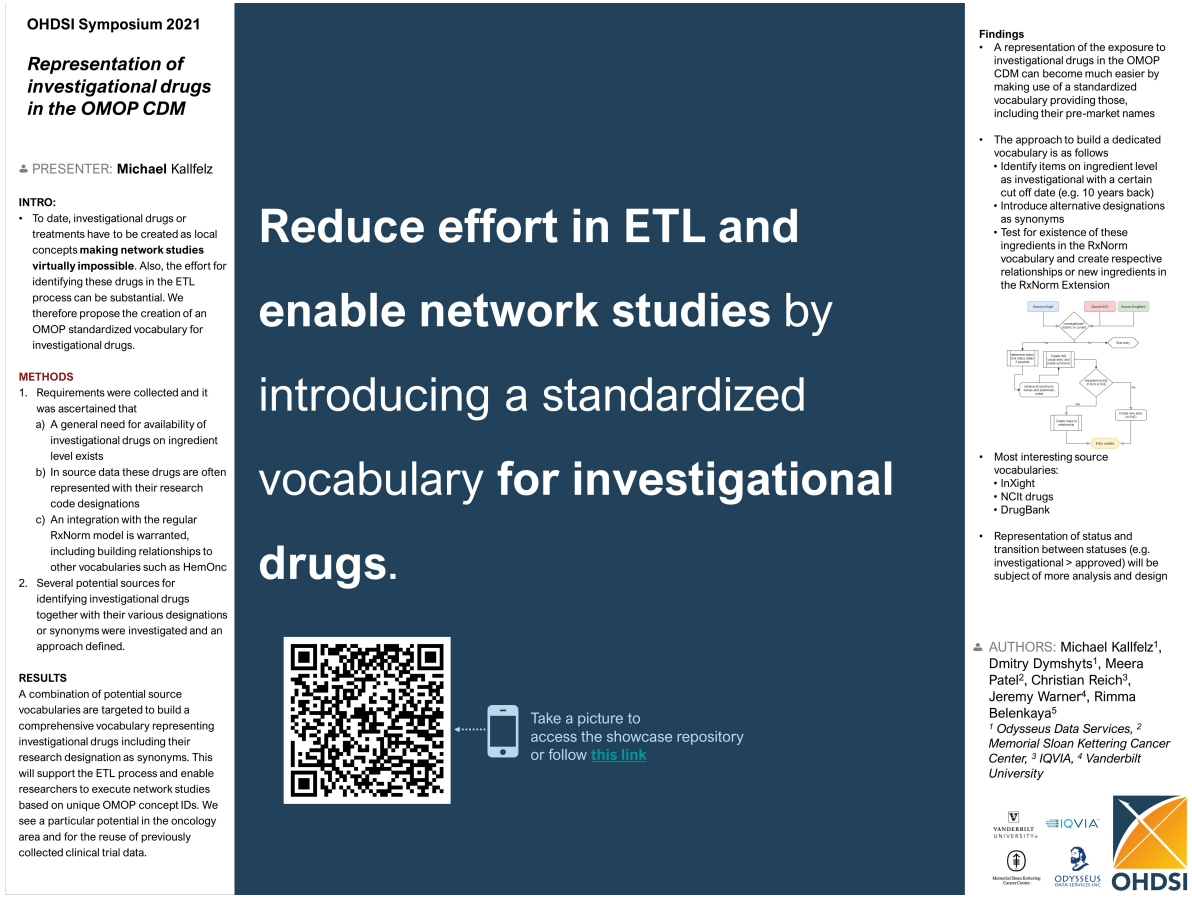
Columbia | Columbia University Department of Biomedical Informatics

THURSDAY

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

#OHDSISocialShowcase This Week



OHDSI Symposium 2021

Representation of investigational drugs in the OMOP CDM

PRESENTER: **Michael** Kallfelz

INTRO:

- To date, investigational drugs or treatments have to be created as local concepts **making network studies virtually impossible**. Also, the effort for identifying these drugs in the ETL process can be substantial. We therefore propose the creation of an OMOP standardized vocabulary for investigational drugs.

METHODS

1. Requirements were collected and it was ascertained that
   a) A general need for availability of investigational drugs on ingredient level exists
   b) In source data these drugs are often represented with their research code designations
   c) An integration with the regular RxNorm model is warranted, including building relationships to other vocabularies such as HemOnc
2. Several potential sources for identifying investigational drugs together with their various designations or synonyms were investigated and an approach defined.

RESULTS

A combination of potential source vocabularies are targeted to build a comprehensive vocabulary representing investigational drugs including their research designation as synonyms. This will support the ETL process and enable researchers to execute network studies based on unique OMOP concept IDs. We see a particular potential in the oncology area and for the reuse of previously collected clinical trial data.

Reduce effort in ETL and enable network studies by introducing a standardized vocabulary **for investigational drugs.**

Take a picture to access the showcase repository or follow this link

Findings

- A representation of the exposure to investigational drugs in the OMOP CDM can become much easier by making use of a standardized vocabulary providing those, including their pre-market names
- The approach to build a dedicated vocabulary is as follows
  - Identify items on ingredient level as investigational with a certain cut off date (e.g. 10 years back)
  - Introduce alternative designations as synonyms
  - Test for existence of these ingredients in the RxNorm vocabulary and create respective relationships or new ingredients in the RxNorm Extension

- Most interesting source vocabularies:
  - InXight
  - NCIt drugs
  - DrugBank
- Representation of status and transition between statuses (e.g. investigational > approved) will be subject of more analysis and design

AUTHORS: Michael Kallfelz[1], Dmitry Dymshyts[1], Meera Patel[2], Christian Reich[3], Jeremy Warner[4], Rimma Belenkaya[5]

[1] Odysseus Data Services, [2] Memorial Sloan Kettering Cancer Center, [3] IQVIA, [4] Vanderbilt University

VANDERBILT UNIVERSITY · IQVIA · Memorial Sloan Kettering Cancer Center · ODYSSEUS DATA SERVICES INC · OHDSI

FRIDAY

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?

Where Are We Now?

Where Are We Going?

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