Connections for Future Collaborations

OHDSI Community Call
Jan. 14, 2025 • 11 am ET

Upcoming Community Calls

Date	Topic
Jan. 14	Connnections for Future Collaborations
Jan. 21	Clinical Guideline Review, Session I
Jan. 28	Clinical Guideline Review, Session II
Feb. 4	First Week of 2025 Workgroup OKRs/Phenotype Phebruary

Three Stages of The Journey

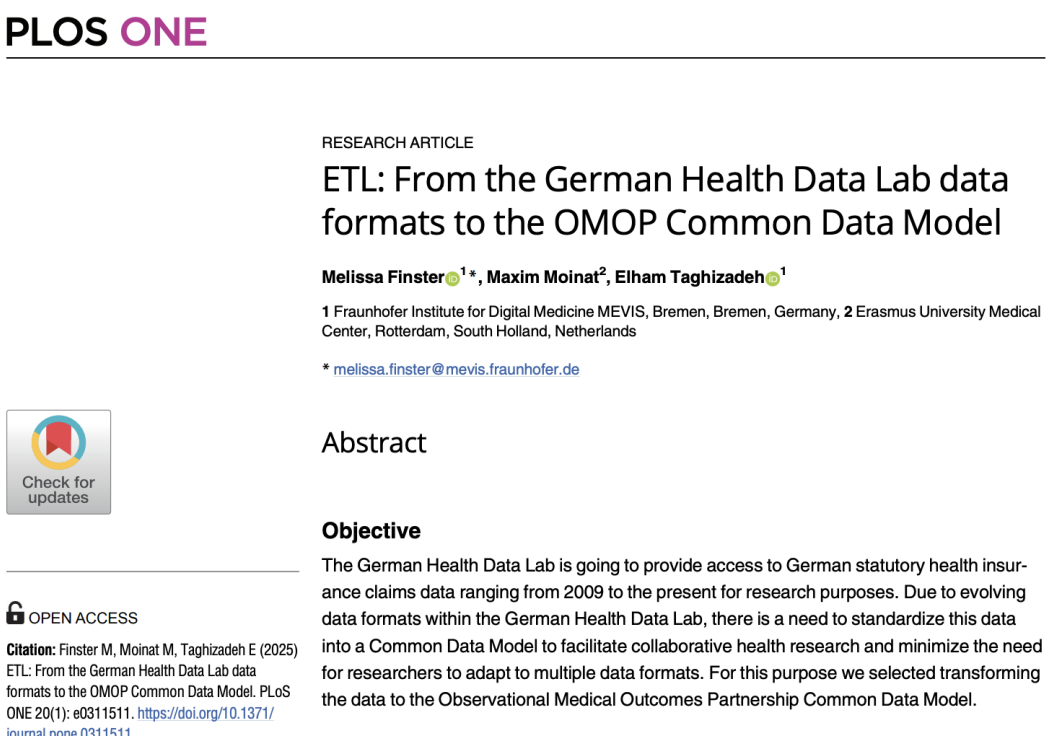
Where Have We Been?

Where Are We Now?

Where Are We Going?

OHDSI Shoutouts!

Congratulations to the team of **Melissa Finster, Maxim Moinat and Elham Taghizadeh** on the publication of **ETL: From the German Health Data Lab data formats to the OMOP Common Data Model** in *PLOS One*.



PLOS ONE

RESEARCH ARTICLE

ETL: From the German Health Data Lab data formats to the OMOP Common Data Model

Melissa Finster[1]*, **Maxim Moinat**[2], **Elham Taghizadeh**[1]

1 Fraunhofer Institute for Digital Medicine MEVIS, Bremen, Bremen, Germany, **2** Erasmus University Medical Center, Rotterdam, South Holland, Netherlands

* melissa.finster@mevis.fraunhofer.de

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OPEN ACCESS

Citation: Finster M, Moinat M, Taghizadeh E (2025) ETL: From the German Health Data Lab data formats to the OMOP Common Data Model. PLoS ONE 20(1): e0311511. https://doi.org/10.1371/journal.pone.0311511

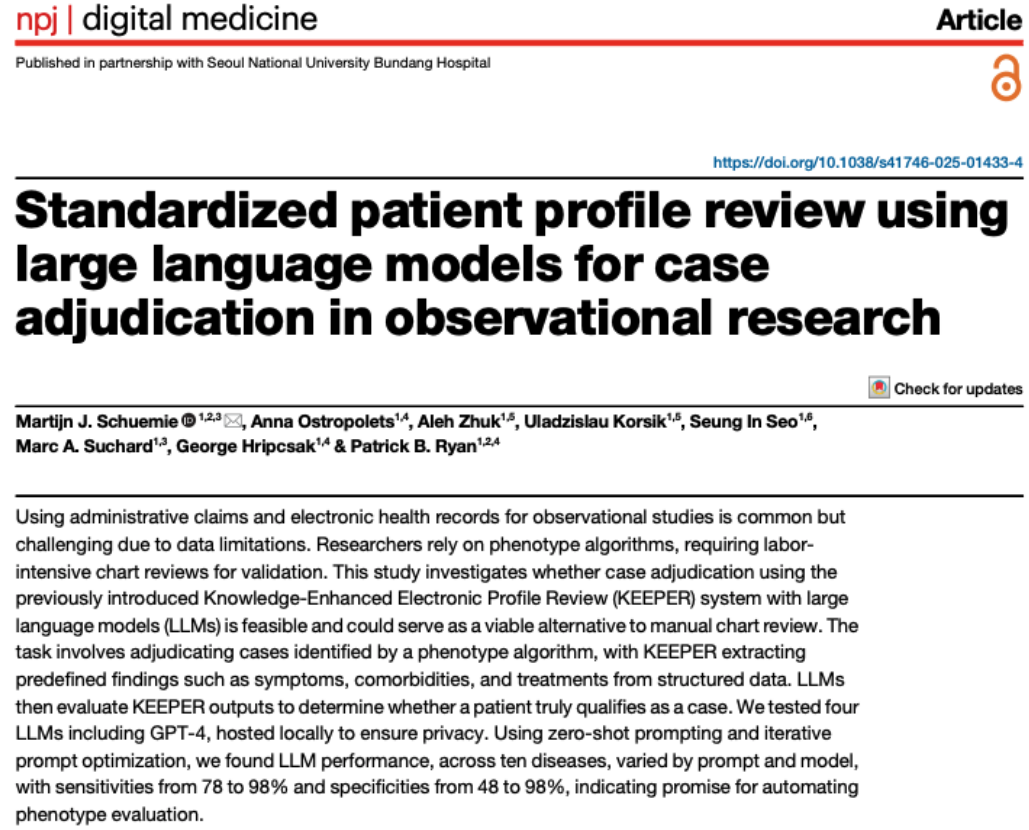
Abstract

Objective

The German Health Data Lab is going to provide access to German statutory health insurance claims data ranging from 2009 to the present for research purposes. Due to evolving data formats within the German Health Data Lab, there is a need to standardize this data into a Common Data Model to facilitate collaborative health research and minimize the need for researchers to adapt to multiple data formats. For this purpose we selected transforming the data to the Observational Medical Outcomes Partnership Common Data Model.

OHDSI Shoutouts!

Congratulations to the team of **Martijn Schuemie, Anna Ostropolets, Aleh Zhuk, Uladzislau Korsik, Seung In Seo, Marc Suchard, George Hripcsak and Patrick Ryan** on the publication of **Standardized patient profile review using large language models for case adjudication in observational research** in *NPJ Digital Medicine.*



npj | digital medicine

Article

Published in partnership with Seoul National University Bundang Hospital

https://doi.org/10.1038/s41746-025-01433-4

Standardized patient profile review using large language models for case adjudication in observational research

Check for updates

Martijn J. Schuemie[1,2,3], Anna Ostropolets[1,4], Aleh Zhuk[1,5], Uladzislau Korsik[1,5], Seung In Seo[1,6], Marc A. Suchard[1,3], George Hripcsak[1,4] & Patrick B. Ryan[1,2,4]

Using administrative claims and electronic health records for observational studies is common but challenging due to data limitations. Researchers rely on phenotype algorithms, requiring labor-intensive chart reviews for validation. This study investigates whether case adjudication using the previously introduced Knowledge-Enhanced Electronic Profile Review (KEEPER) system with large language models (LLMs) is feasible and could serve as a viable alternative to manual chart review. The task involves adjudicating cases identified by a phenotype algorithm, with KEEPER extracting predefined findings such as symptoms, comorbidities, and treatments from structured data. LLMs then evaluate KEEPER outputs to determine whether a patient truly qualifies as a case. We tested four LLMs including GPT-4, hosted locally to ensure privacy. Using zero-shot prompting and iterative prompt optimization, we found LLM performance, across ten diseases, varied by prompt and model, with sensitivities from 78 to 98% and specificities from 48 to 98%, indicating promise for automating phenotype evaluation.

OHDSI Shoutouts!

Congratulations to the team of **Noah Hong, Yeh-Hee Ko, Jeong Hyun Park, Eun Jin Ha, Sung Ho Lee, Kang Min Kim, Hyun-Seung Kang, Jeong Eun Kim, Kwangsoo Kim, and Won-Sang Cho** on the publication of **Impact of Uric Acid Levels on Mortality and Cardiovascular Outcomes in Relation to Kidney Function** in the *Journal of Clinical Neuroscience*.

Journal of Clinical Neuroscience 133 (2025) 111039

Contents lists available at ScienceDirect

Journal of Clinical Neuroscience

journal homepage: www.journals.elsevier.com/journal-of-clinical-neuroscience

A common data model for oral anticoagulants-related risk of spontaneous intracranial hemorrhage

Noah Hong [a,1], Yeh-Hee Ko [b,1], Jeong Hyun Park [c,d], Eun Jin Ha [e,g], Sung Ho Lee [g], Kang Min Kim [g], Hyun-Seung Kang [g], Jeong Eun Kim [g], Kwangsoo Kim [f,*], Won-Sang Cho [g,*]

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ARTICLE INFO

Keywords:
Warfarin
Non-vitamin K antagonist oral anticoagulants
Risk factors
Spontaneous intracranial hemorrhage
Common data model

ABSTRACT

Spontaneous intracranial hemorrhage (sICH) is a major complication associated with oral anticoagulation which results in a high mortality rate, and the incidence of anticoagulant-induced sICH has increased markedly, so it is necessary to investigate the risk of anticoagulation-related sICH in a real-world setting. We aimed to investigate the incidence and risk factors of oral anticoagulant-related sICH using a common data model (CDM), and to determine whether a clinical study using the CDM would be comparable to conventional studies. After converting the various clinical codes of 12,821 patients taking oral anticoagulants, such as warfarin and non-vitamin K antagonist oral anticoagulants (NOACs), into the Observational Medical Outcomes Partnership (OMOP) CDM format, we analyzed the incidence and risk factors of sICH. sICH occurred in 0.5 % of 5,626 patients with warfarin and 0.2 % of 7,195 patients with NOAC. The mean duration of warfarin and NOACs before sICH occurrence was 251.4 ± 373.6 and 124.2 ± 135.7 days, respectively. Multivariable analysis showed significant risk factors of the sICH, such as warfarin over NOACs; hypertension; diabetes mellitus; brain tumors; and decreased duration of oral anticoagulation. NOACs demonstrated a lower risk of sICH than warfarin in a real-world setting using OMOP CDM confined to a single institution. Clinical studies using a CDM for the multi-center datasets may provide more reliable information about the risk of sICH.

OHDSI Shoutouts!

Congratulations to the team of **Young-Eun Kwon, Shin-Young Ahn, Gang-Jee Ko, Young-Joo Kwon and Ji-Eun Kim** on the publication of **Impact of Uric Acid Levels on Mortality and Cardiovascular Outcomes in Relation to Kidney Function** in the *Journal of Clinical Neuroscience*.

Journal of *Clinical Medicine*

MDPI

Article

Impact of Uric Acid Levels on Mortality and Cardiovascular Outcomes in Relation to Kidney Function

Young-Eun Kwon [1], Shin-Young Ahn [1,2], Gang-Jee Ko [1,2], Young-Joo Kwon [1,2] and Ji-Eun Kim [1,2,*]

[1] Department of Internal Medicine, Korea University Guro Hospital, Seoul 08308, Republic of Korea; eunkoda@naver.com (Y.-E.K.)
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Abstract: Background: Uric acid levels are linked to cardiovascular outcomes and mortality, especially in chronic kidney disease (CKD). However, their impact across varying kidney function remains unclear. **Methods**: We conducted a retrospective cohort study using the Observational Medical Outcomes Partnership Common Data Model (OMOP-CDM) database from a single center. Adult patients with at least one serum uric acid measurement between 2002 and 2021 were included and categorized by estimated glomerular filtration rate (eGFR): normal kidney function (≥90 mL/min/1.73 m^2), mild dysfunction (60–89 mL/min/1.73 m^2), moderate dysfunction (30–59 mL/min/1.73 m^2), and advanced dysfunction (<30 mL/min/1.73 m^2). The primary outcome was all-cause mortality with secondary outcomes being myocardial infarction (MI) and heart failure (HF). **Results**: A total of 242,793 participants were analyzed. Uric acid levels showed a U-shaped association with all-cause mortality in advanced kidney dysfunction, where both low (<3 mg/dL) and high (>10 mg/dL) levels increased mortality risk. In mild kidney dysfunction, lower uric acid levels were linked to better survival. HF risk increased linearly with higher uric acid, particularly in normal kidney function, while no significant association was found between uric acid and MI in any group. **Conclusions**: Uric acid levels are associated with mortality in a U-shaped pattern for advanced kidney dysfunction, while lower levels appear protective in mild dysfunction. These findings suggest the need for personalized uric acid management in CKD patients based on their kidney function.

check for updates

Academic Editor: Laetitia Dou

Received: 8 October 2024
Revised: 5 December 2024

Keywords: uric acid; kidney dysfunction; chronic kidney disease; mortality; cardiovascular

OHDSI Shoutouts!

Congratulations to the team of **Mitchell Conover, Patrick Ryan, Yong Chen, Marc Suchard, George Hripcsak, and Martijn Schuemie** on the publication of **Objective study validity diagnostics: a framework requiring pre-specified, empirical verification to increase trust in the reliability of real-world evidence** in *JAMIA.*

Journal of the American Medical Informatics Association, 2025, 1–8
https://doi.org/10.1093/jamia/ocae317
Research and Applications

Research and Applications

Objective study validity diagnostics: a framework requiring pre-specified, empirical verification to increase trust in the reliability of real-world evidence

Mitchell M. Conover, PhD[1,2,*], Patrick B. Ryan, PhD[1,2,3], Yong Chen, PhD[1,4], Marc A. Suchard, MD, PhD[1,5,6], George Hripcsak, MD[1,3], Martijn J. Schuemie, PhD[1,2,5]

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Abstract

Objective: Propose a framework to empirically evaluate and report validity of findings from observational studies using pre-specified objective diagnostics, increasing trust in real-world evidence (RWE).

Materials and Methods: The framework employs objective diagnostic measures to assess the appropriateness of study designs, analytic assumptions, and threats to validity in generating reliable evidence addressing causal questions. Diagnostic evaluations should be interpreted before the unblinding of study results or, alternatively, only unblind results from analyses that pass pre-specified thresholds. We provide a conceptual overview of objective diagnostic measures and demonstrate their impact on the validity of RWE from a large-scale comparative new-user study of various antihypertensive medications. We evaluated expected absolute systematic error (EASE) before and after applying diagnostic thresholds, using a large set of negative control outcomes.

Results: Applying objective diagnostics reduces bias and improves evidence reliability in observational studies. Among 11 716 analyses (EASE-=0.38), 13.9% met pre-specified diagnostic thresholds which reduced EASE to zero. Objective diagnostics provide a comprehensive and empirical set of tests that increase confidence when passed and raise doubts when failed.

Discussion: The increasing use of real-world data presents a scientific opportunity; however, the complexity of the evidence generation process poses challenges for understanding study validity and trusting RWE. Deploying objective diagnostics is crucial to reducing bias and improving reliability in RWE generation. Under ideal conditions, multiple study designs pass diagnostics and generate consistent results, deepening understanding of causal relationships. Open-source, standardized programs can facilitate implementation of diagnostic analyses.

Conclusion: Objective diagnostics are a valuable addition to the RWE generation process.

Key words: observational study; research design; data interpretation, statistical; methods; causality.

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	12 pm	Generative AI and Analytics
Wednesday	8 am	Psychiatry
Thursday	8 am	India Community Call
Thursday	10 am	Themis
Thursday	11 am	Industry
Thursday	12 pm	HADES
Thursday	7 pm	Dentistry
Friday	10 am	GIS-Geographic Information System
Friday	10:30 am	Open-Source Community
Friday	11:30 am	Steering
Friday	11:30 am	Clinical Trials
Monday	10 am	Getting Started (Healthcare Systems sub-workgroup)
Monday	10 am	Africa Chapter
Monday	11 am	Data Bricks User Group
Monday	2 pm	Electronic Animal Health Records

Next CBER Best Seminar: Jan. 15

Topic: Emulation of Target Trial on Vaccinations During Pregnancy

Presenter: Sonia Hernández-Díaz, MD, DrPH, Professor of Epidemiology, Harvard T.H. Chan School of Public Health

Date/Time: Jan. 15, 11 am ET

ohdsi.org/cber-best-seminar-series

Guideline-Driven Opportunities

Guideline-driven evidence generation opportunities

Chungsoo_Kim 7d

Treating obesity is receiving tremendous attention these days. The attached links are clinical guidelines for obesity management.

2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults 2

Thamir 1d

Thanks @Patrick_Ryan, for discussing this very interesting and bright idea. I go with what @Chungsoo_Kim mentioned especially the new standard of care of care guidelines (2025) https://diabetesjournals.org/care/article/48/Supplement_1/S6/157564/Summary-of-Revisions-Standards-of-Care-in-Diabetes . In these guidelines, there were some updated recommendations for the use of new dual GIP and GLP medications. Also, the role of SGLT2 inhibitors in MACE and HF. These might be discussed in the LEGEND studies but also can be studied further especially comparing combinations with mono therapy, or event safety profile.

Another area I guess it is not touched much is the depression treatments, a recent guideline Canadian Network for Mood and Anxiety Treatments (CANMAT) 2023 Update on Clinical Guidelines for Management of Major Depressive Disorder in Adults discussed the different medications for depression. Treatment Guidelines: Depression | aapp.org
As you know, these medications have benefits but not sure if there were any comparison between different groups like **SSRI**, **TCAs**, or **SNRI** or others. Also, these medications have big concerns about their safety that also can be discussed. I am not really expert in these areas and I am sure there are who know better than me, but **I thought I'd open this up** for future discussion.

We're currently in the process of developing analysis tools that address these gaps in specific disease areas and treatment stages.

We'd love to hear your thoughts!

Gowtham Rao 6d
agolozar Asieh Golozar 3h

Cancer guidelines are often large, intricate, and subject to frequent updates due to multifaceted nature of the disease. Cancer is not a single disease but a collection of hundreds of different conditions, each with its own biology, behavior, and response to treatment. This requires guidelines to account for a wide range of variables such as tumor type, stage, genetic mutations, and patient characteristics. Additionally, cancer treatment often involves multidisciplinary approaches, including surgery, radiation, chemotherapy, immunotherapy, and targeted therapies, further complicating the decision-making process.

Several organizations publish guidelines but let us focus on NCCN guidelines, these are step-by-step decision trees for each cancer type all the way down the possible decision points. Unfortunately, the guidelines are much less specific than one would expect. It's full of sentences like:

- "With the recent changes to first-line treatment options for metastatic disease, many providers are moving towards immune checkpoint inhibitor combinations, such as enfortumab - vedotin plus pembrolizumab, as a first-line treatment option. In this evolving paradigm, there is limited evidence to guide the optimal selection of second- and subsequent-line therapies following these new first-line regimens." — NCCN Bladder Cancer
- "Clinical trial enrollment is recommended by the NCCN Panel for all patients when appropriate, but is strongly recommended for second-line and subsequent therapies, as data for locally advanced or metastatic disease treated with subsequent-line therapy are highly variable." — NCCN Bladder Cancer
- "The optimal sequencing of systemic therapy and resection remains unclear." — NCCN Colon Cancer

Bottom line: We have large and complicated decision trees, somewhat fuzzy, with each node its own constellation. Most of them are based on clinical trials. With respect to RWE, we could create evidence for each node about:

forums.ohdsi.org

Workgroup OKRs

Each year, workgroup representatives join a February community call to present the mission, objectives and key results for their respective groups. These 2-4 minute presentations are recorded and posted on the Workgroups homepage on OHDSI.org.

Please choose a date to sign up for a February date; once a date has at least 10 workgroups, it will be closed.

The Center for Advanced Healthcare Research Informatics (CAHRI) at Tufts Medicine welcomes:

Vipina Keloth, PhD

Associate Research Scientist in Biomedical Informatics and Data Science at Yale University School of Medicine

'Exploring the realm of large language models for information extraction in the biomedical domain'

January 23, 2025, 11am-12pm EST
Virtually via Zoom

Please contact Marty Alvarez at malvarez2@tuftsmedicalcenter.org for calendar invite or questions.

TuftsMedicine
Tufts Medical Center

CDM Survey Subgroup Landscape Assessment

The CDM Survey Subgroup invites colleagues who have or are going to design, develop, and/or implement research surveys and use them with the OMOP CDM to share information about those efforts by completing this survey. Your completion of this 10-15 minute survey will provide information to the CDM workgroup about OMOP utilization among survey research teams. The CDM Survey subgroup is a collaborative effort, led by a team at the National Cancer Institute, to develop standardized approaches and best practices for helping research teams better integrate survey data elements into the OMOP common data model.

The deadline has been extended to mid-January.

LANDSCAPE ASSESSMENT

- **Activities**
  - Invite representatives from cohorts with experience using the CDM for survey data to share their knowledge and challenges.
  - Conduct a community survey to gather information on experiences and needs related to survey data in the CDM.
  - Review the most used Common Data Elements (CDMs) as a foundation for developing standards, tools, and best practices.
- **Key Result**
  - A comprehensive report summarizing survey CDM mapping resources, challenges, and identified development priorities (vocabulary, standards, tools, best practices) to be shared with the OHDSI community.

WHO SHOULD PARTICIPATE

- You have survey data and you've mapped it to the OMOP CDM
- You have survey data and you would like to map it to the OMOP CDM
- You are in the process of developing a survey(s) and plan to map to the OMOP CDM
- Multiple perspectives from the same team
- Multiple surveys from the same person

#OHDSISocialShowcase This Week

Monday

Lessons from mapping cancer information from European hospitals to ICD-O-3 conditions in OMOP

(Lars Halvorsen, Olivier Bouissou, Elisabeth Ross, Stelios Theophanous, Joëlle Thonnard, Piers Mahon)

Lessons from mapping cancer information from European hospitals to ICD-O-3 conditions in OMOP

PRESENTER: **Lars Halvorsen**

INTRODUCTION

- European hospitals in the DigiONE network[1] face a recurring conversion challenge in mapping cancer conditions.
- The hospitals mapped their cancer diagnoses to ICD-O-3 or SNOMED using topography and morphology information from pathology reports or electronic healthcare records.
- Differences in terminologies used at source presented different challenges for different hospitals.
- A sizeable subset of ICD-O-3 diagnosis codes were found to not yet be defined in the OHDSI vocabularies[2].

METHODS

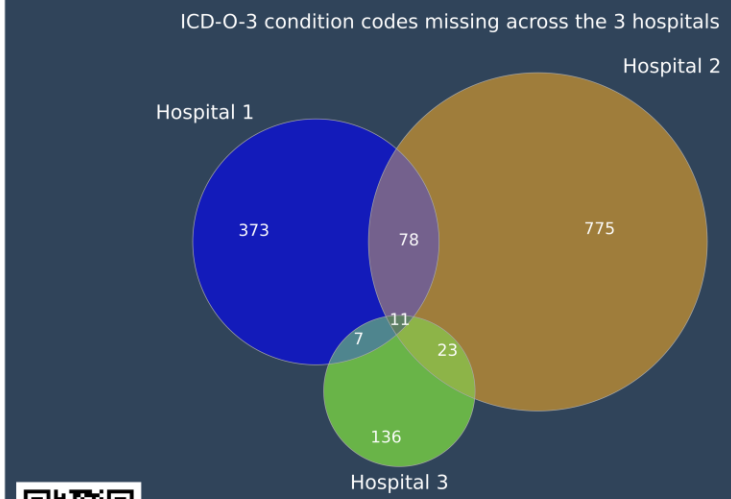
Different paths for mappings to ICD-O-3 condition concepts:

Hospital 1:
- ICD-O-3 condition codes derived from ICD-O-3 morphology and topography codes.

Hospital 2:
- Pathology results coded in terminology based on old SNOMED version.
- Most T codes correspond to current SNOMED concept, while most M codes had equivalent ICD-O-3 morphology code.
- These T and M codes were combined to ICD-O-3 condition concepts, with some exceptions needing special mapping.

Hospital 3:
- ICD-O-3 topography and ICD-O-3 morphology codes available in the source system.
- Direct construction of ICD-O-3 condition codes.

Including additional ICD-O-3 condition concepts in the OHDSI vocabularies will facilitate cancer research across hospitals



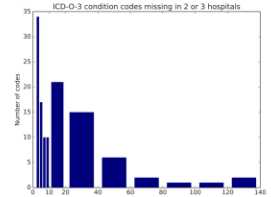
Take a picture to download the full abstract

RESULTS

- All 3 hospitals had ICD-O-3 condition codes not yet available in the OHDSI vocabularies. 119 such missing codes appeared in at least two of the three hospitals (see abstract for full list).

Solid and haematological cancers		Hospital 1	Hospital 2	Hospital 3
OHDSI vocabulary version		v5.0 29-FEB-24	v5.0 23-JAN-23	v5.0 29-FEB-24
Source	ICD-O-3 source data	ICD-10 diagnosis codes (converted to ICD-O-3 topography) + ICD-O-3 morphology	Local pathology vocabulary for topography and morphology	ICD-O-3 topography + ICD-O-3 morphology
	# unique source codes	3588	2979	1823
Mapping Result	# standard ICD-O-3 Condition concept ID	2413	1524	1308
	# non-standard ICD-O-3 Condition concept IDs mapped to standard (SNOMED) concept IDs	706	568	338
	# ICD-O-3 Condition codes with no concept ID in vocabulary	469	887	177

- Of these missing codes, 53 have already been identified for inclusion in a future OHDSI vocabulary release, while 66 of these codes had not yet been included.
- The DigiONE hospitals will further evaluate these findings and work with the Oncology WG - Vocabulary subgroup to include an additional set of ICD-O-3 condition codes considered as relevant.



The majority of codes missing in 2 or 3 hospitals were rarely used for coding cancer, with 71 codes used less than 10 times. Only a few codes were used more frequently, with 4 codes used between 80 and 140 times.

References

1. Mahon, P., Chatzitheofilou, I., Dekker, A. et al. *A federated learning system for precision oncology in Europe: DigiONE.* Nat Med 30, 334–337 (2024). https://doi.org/10.1038/s41591-023-02715-8
2. Prinsen P, van Swieten M, Attanasio C, Enarly E, Lanenningen S, Rapiti E, Fournier E, Künzli P, Schnell M, Marcic D, Coulfignal S, Backes C. *Mapping of ICD-O-3 codes to standard concepts: Lessons learned from four population-based cancer registries.* OHDSI Europe Symposium 2023. https://ohdsi-europe.org/images/symposium-2023/posters/poster_OHDSI_symposium_ICDO3_Peter_Prinsen_-_Peter_Prinsen.pdf

Authors: Lars Halvorsen, Olivier Bouissou, Elisabeth Ross, Stelios Theophanous, Joëlle Thonnard, Piers Mahon

Oslo University Hospital · The Leeds Teaching Hospitals NHS Trust · INSTITUT ROI ALBERT II · edence Health · DigiCore

#OHDSISocialShowcase This Week

Tuesday

Jackalope Plus Performance: Benchmarking and Competitors

(Denys Kaduk, Bohdan Khilchevskyi, Maksym Trofymenko, Tetiana Nesmiian, Polina Talapova, Max Ved, Inna Ageeva)

Jackalope Plus Performance: Benchmarking and Competitors

PRESENTER:
Polina Talapova

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INTRO

In the healthcare domain, where data plays an increasingly crucial role, accurate and efficient mapping of medical terminologies is fundamental. This mapping ensures seamless data exchange (interoperability) between different healthcare information systems, facilitates clinical research efforts, and ultimately improves patient care. The advent of the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) has further emphasized the significance of terminology mapping.

While manual mapping remains an option, it is a laborious and time-consuming process, hindering large-scale data standardization initiatives. To address this challenge, several automated mapping tools have emerged, aiming to streamline the process and enhance efficiency. This study benchmarks Jackalope Plus, a prominent mapping tool, against manual mapping and Usagi, another automated option, to assess their relative strengths and weaknesses.

METHODS

Three domain experts (testers) familiar with all mapping methods and assigned tasks based on their preferences. The benchmark utilized a newly created dataset comprising unmapped concepts from MeSH and CIEL, as well as some concepts created by our team expert. The test set was provided to the testers prior to the mapping process, formatted as a CSV file with a semicolon (;) delimiter containing 40 unmapped concepts.

Three methods were used:

1. Manual mapping
2. Usagi mapping
3. Jackalope Plus mapping

Each mapping method followed specific steps, described at the center of the poster..

Jackalope+

The fastest Rabbit in a family...
and with Horns!

METHODS:

Manual mapping

- Upload list of unmapped concepts to a text redactor
- Set relationship and compliancesusing Athena browser

Usagi mapping

- Download Usagi and the necessary vocabulary archives
- Update CPT names
- Build an index within Usagi
- Upload list of unmapped concepts
- Set the filtering options
- Review and approval of mappings

Jackalope+ mapping

- Convert list of unmapped concepts to a format compatible with Jackalope
- Logging in Jackalope
- Upload the CSV file and Select the appropriate delimeter
- Mapping process is completed

RESULTS:

Time in minutes	Method		
	Manual	Usagi	Jackalope
Time required for dataset preparation	4	5	1
Time for mapping process	104	35	27
Mapping Results			
Correct mapping	29	21	31
Ambiguous/not full mapping	5	7	6
Wrong mapping	6	11	3

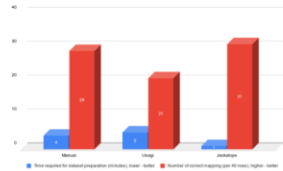
A joke. How do we call people who haven't tried to map with Jackalope?

Jackalopeless.

And those, who tried?

Horned Hare Heroes!

RESULTS



Results are presented in the left lower corner and briefly on a diagram above. The time for preparation is not included in the final results due to the variability of the source data.

The benchmarking process revealed significant insights into the efficiency and accuracy of the mapping tools compared. Both Jackalope Plus and Usagi demonstrated the ability to significantly reduce the time required for the mapping process compared to manual methods. This time efficiency is critical in large-scale data standardization efforts, where speed and accuracy are paramount.

However, the quality of the results varied between the tools. Jackalope Plus consistently produced more accurate mappings than Usagi. This superior accuracy can be attributed to Jackalope Plus's advanced algorithms and streamlined workflow, which minimize errors and enhance precision. The domain experts reported that Jackalope Plus not only reduced the time spent on mapping but also delivered higher-quality results, making it a more reliable tool for integrating medical data into standardized frameworks.

THE TEAM:

Denys Kaduk, Bohdan Khilchevskyi, Maksym Trofymenko, Tetiana Nesmiian, Polina Talapova, Max Ved, Inna Ageeva

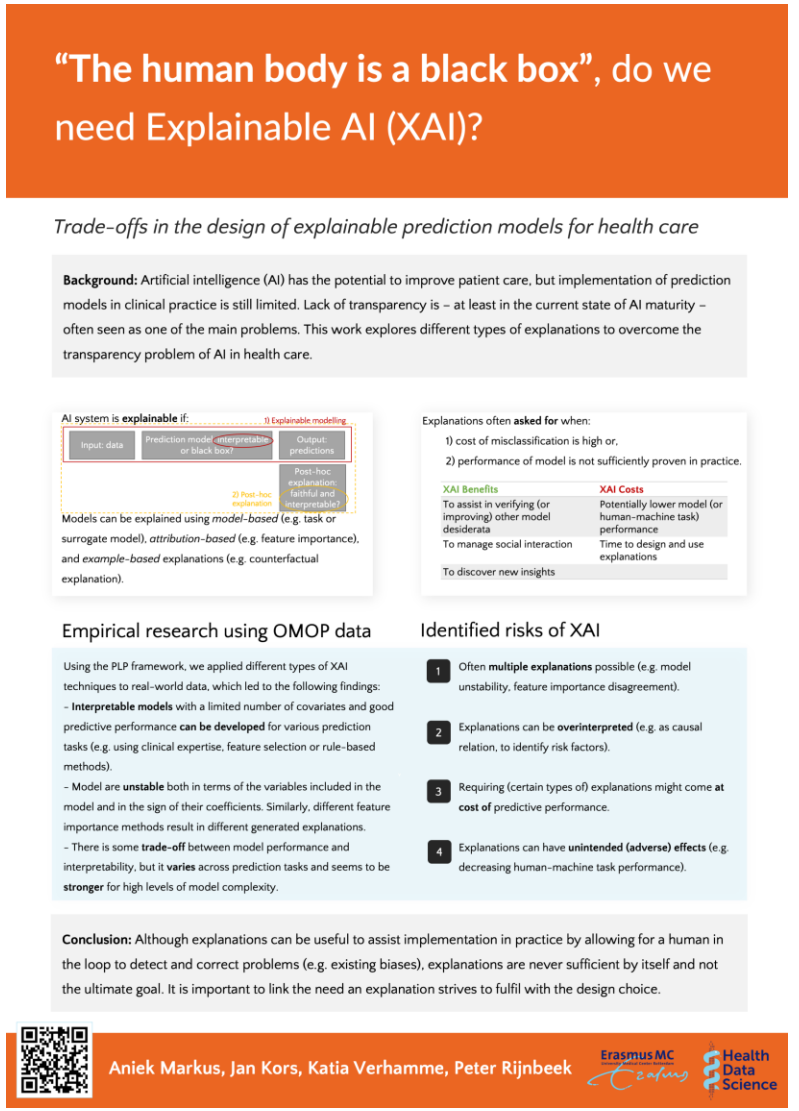
sciforce OHDSI

#OHDSISocialShowcase This Week

Wednesday

Trade-offs in the design of explainable prediction models for health care

(Aniek F. Markus, Jan A. Kors, Katia M.C. Verhamme, Peter R. Rijnbeek)

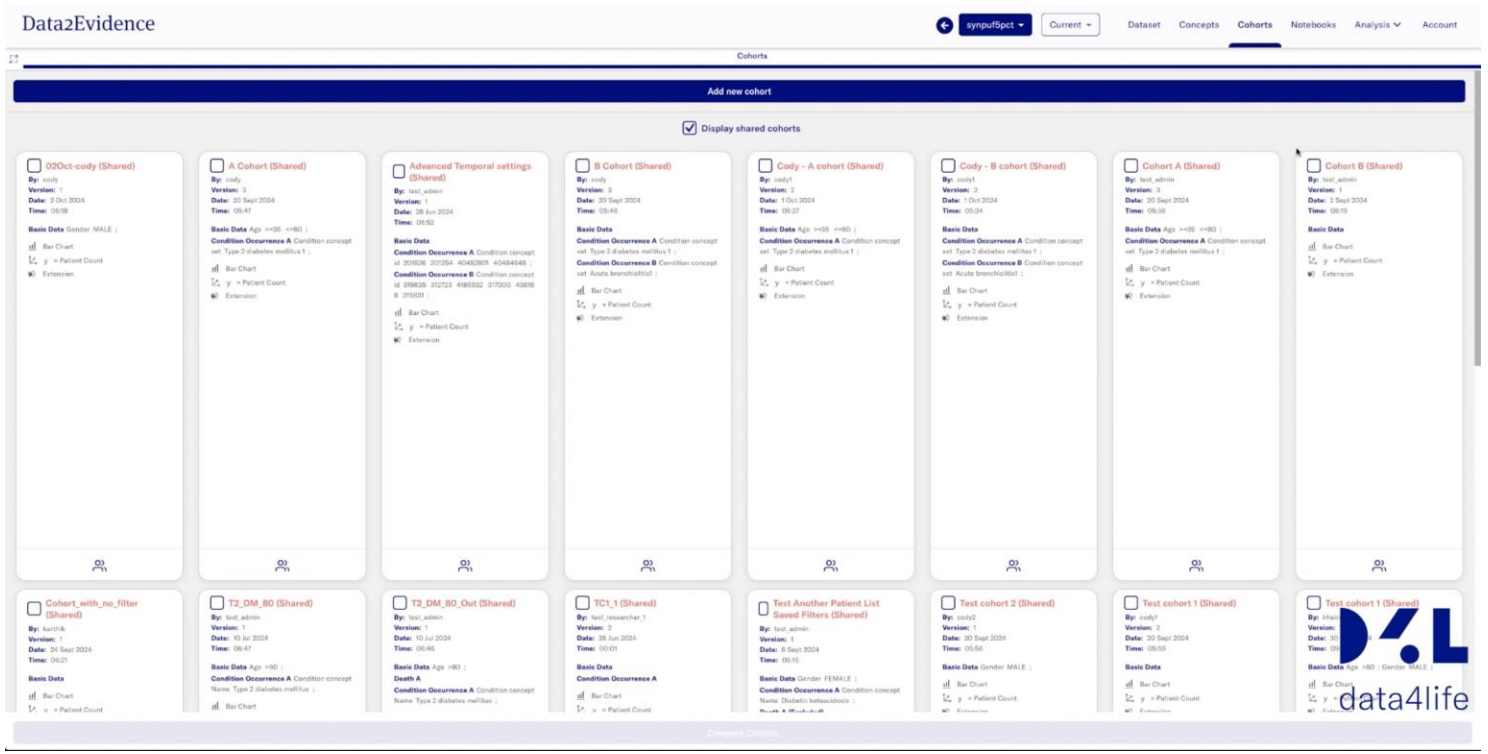


#OHDSISocialShowcase This Week

Thursday

An interactive approach for data exploration and phenotyping in the Data2Evidence platform

(Satish Anbazhagan, Peter Hoffmann)

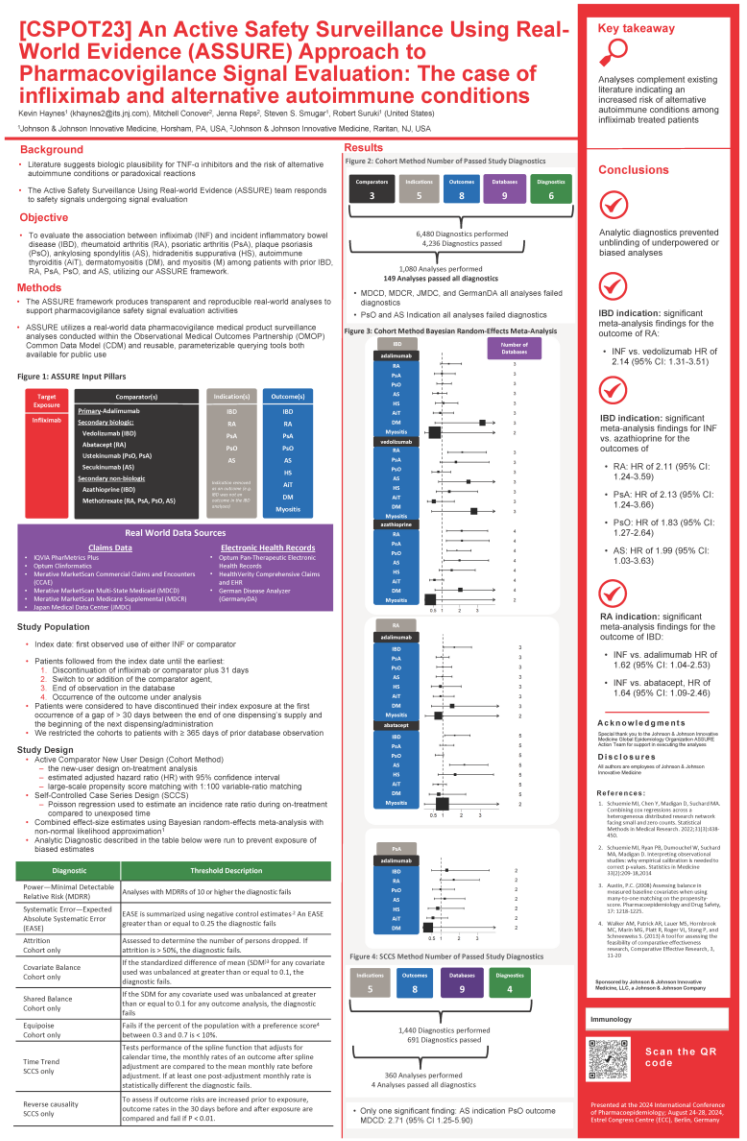


#OHDSISocialShowcase This Week

Friday

An Active Safety Surveillance Using Real-World Evidence (ASSURE) Approach to Pharmacovigilance Signal Evaluation: The case of infliximab and alternative autoimmune conditions

(Kevin Haynes, Mitchell M. Conover, Jenna Reps, Steven S. Smugar, Robert Suruki)



[CSPOT23] An Active Safety Surveillance Using Real-World Evidence (ASSURE) Approach to Pharmacovigilance Signal Evaluation: The case of infliximab and alternative autoimmune conditions

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Background

- Literature suggests biologic plausibility for TNF-α inhibitors and the risk of alternative autoimmune conditions or paradoxical reactions
- The Active Safety Surveillance Using Real-world Evidence (ASSURE) team responds to safety signals undergoing signal evaluation

Objective

- To evaluate the association between infliximab (INF) and incident inflammatory bowel disease (IBD), rheumatoid arthritis (RA), psoriatic arthritis (PsA), plaque psoriasis (PsO), ankylosing spondylitis (AS), hidradenitis suppurativa (HS), autoimmune thyroiditis (AIT), dermatomyositis (DM), and myositis (M) among patients with prior IBD, RA, PsA, PsO, and AS, utilizing our ASSURE framework.

Methods

- The ASSURE framework produces transparent and reproducible real-world analyses to support pharmacovigilance safety signal evaluation activities
- ASSURE utilizes a real-world data pharmacovigilance medical product surveillance analyses conducted within the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) and reusable, parameterizable querying tools both available for public use

Figure 1: ASSURE Input Pillars

Target Exposure	Comparator(s)	Indication(s)	Outcome(s)
Infliximab	Primary: Adalimumab Secondary biologic: Vedolizumab (IBD) Abatacept (RA) Ustekinumab (PsO, PsA) Secukinumab (AS) Secondary non-biologic Azathioprine (IBD) Methotrexate (RA, PsA, PsO, AS)	IBD RA PsA PsO AS	IBD RA PsA PsO AS HS AIT DM Myositis

Real World Data Sources

Claims Data
- IQVIA PharMetrics Plus
- Optum Clinformatics
- Merative MarketScan Commercial Claims and Encounters (CCAE)
- Merative MarketScan Multi-State Medicaid (MDCD)
- Merative MarketScan Medicare Supplemental (MDCR)
- Japan Medical Data Center (JMDC)

Electronic Health Records
- Optum Pan-Therapeutic Electronic Health Records
- HealthVerity Comprehensive Claims and EHR
- German Disease Analyzer (GermanyDA)

Study Population

- Index date: first observed use of either INF or comparator
- Patients followed from the index date until the earliest:
  1. Discontinuation of infliximab or comparator plus 31 days
  2. Switch to or addition of the comparator agent,
  3. End of observation in the database
  4. Occurrence of the outcome under analysis
- Patients were considered to have discontinued their index exposure at the first occurrence of a gap of > 30 days between the end of one dispensing's supply and the beginning of the next dispensing/administration
- We restricted the cohorts to patients with ≥ 365 days of prior database observation

Study Design

- Active Comparator New User Design (Cohort Method)
  - the new-user design on-treatment analysis
  - estimated adjusted hazard ratio (HR) with 95% confidence interval
  - large-scale propensity score matching with 1:100 variable-ratio matching
- Self-Controlled Case Series Design (SCCS)
  - Poisson regression used to estimate an incidence rate ratio during on-treatment compared to unexposed time
- Combined effect-size estimates using Bayesian random-effects meta-analysis with non-normal likelihood approximation[1]
- Analytic Diagnostic described in the table below were run to prevent exposure of biased estimates

Diagnostic	Threshold Description
Power—Minimal Detectable Relative Risk (MDRR)	Analyses with MDRRs of 10 or higher the diagnostic fails
Systematic Error—Expected Absolute Systematic Error (EASE)	EASE is summarized using negative control estimates[2] An EASE greater than or equal to 0.25 the diagnostic fails
Attrition Cohort only	Assessed to determine the number of persons dropped. If attrition is > 50%, the diagnostic fails.
Covariate Balance Cohort only	If the standardized difference of mean (SDM)[3] for any covariate used was unbalanced at greater than or equal to 0.1, the diagnostic fails.
Shared Balance Cohort only	If the SDM for any covariate used was unbalanced at greater than or equal to 0.1 for any outcome analysis, the diagnostic fails
Equipoise Cohort only	Fails if the percent of the population with a preference score[4] between 0.3 and 0.7 is < 10%.
Time Trend SCCS only	Tests performance of the spline function that adjusts for calendar time, the monthly rates of an outcome after spline adjustment are compared to the mean monthly rate before adjustment. If at least one post-adjustment monthly rate is statistically different the diagnostic fails.
Reverse causality SCCS only	To assess if outcome risks are increased prior to exposure, outcome rates in the 30 days before and after exposure are compared and fail if P < 0.01.

Results

Figure 2: Cohort Method Number of Passed Study Diagnostics

Comparators	Indications	Outcomes	Databases	Diagnostics
3	5	8	9	6

6,480 Diagnostics performed
4,236 Diagnostics passed

1,080 Analyses performed
149 Analyses passed all diagnostics

- MDCD, MDCR, JMDC, and GermanDA all analyses failed diagnostics
- PsO and AS Indication all analyses failed diagnostics

Figure 3: Cohort Method Bayesian Random-Effects Meta-Analysis

Figure 4: SCCS Method Number of Passed Study Diagnostics

Indications	Outcomes	Databases	Diagnostics
5	8	9	4

1,440 Diagnostics performed
691 Diagnostics passed

360 Analyses performed
4 Analyses passed all diagnostics

- Only one significant finding: AS indication PsO outcome MDCD: 2.71 (95% CI 1.25-5.90)

Key takeaway

Analyses complement existing literature indicating an increased risk of alternative autoimmune conditions among infliximab treated patients

Conclusions

Analytic diagnostics prevented unblinding of underpowered or biased analyses

IBD indication: significant meta-analysis findings for the outcome of RA:
- INF vs. vedolizumab HR of 2.14 (95% CI: 1.31-3.51)

IBD indication: significant meta-analysis findings for INF vs. azathioprine for the outcomes of
- RA: HR of 2.11 (95% CI: 1.24-3.59)
- PsA: HR of 2.13 (95% CI: 1.24-3.66)
- PsO: HR of 1.83 (95% CI: 1.27-2.64)
- AS: HR of 1.99 (95% CI: 1.03-3.63)

RA indication: significant meta-analysis findings for the outcome of IBD:
- INF vs. adalimumab HR of 1.62 (95% CI: 1.04-2.53)
- INF vs. abatacept, HR of 1.64 (95% CI: 1.09-2.46)

Acknowledgments

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Disclosures

All authors are employees of Johnson & Johnson Innovative Medicine

References:

1. Schuemie MJ, Chen Y, Madigan D, Suchard MA. Combining cox regressions across a heterogeneous distributed research network facing small and zero-counts. Statistical Methods in Medical Research. 2022;31(3):438-450.
2. Schuemie MJ, Ryan PB, Dumouchel W, Suchard MA, Madigan D. Interpreting observational studies: why empirical calibration is needed to correct p-values. Statistics in Medicine. 33(2):209-18,2014
3. Austin, P.C. (2008) Assessing balance in measured baseline covariates when using many-to-one matching on the propensity score. Pharmacoepidemiology and Drug Safety, 17: 1218-1225.
4. Walker AM, Patrick AR, Lauer MS, Hornbrook ME, Marin MG, Platt R, Roger VL, Stang P, and Schneeweiss S. (2013) A tool for assessing the feasibility of comparative effectiveness research, Comparative Effective Research, 3, 11-20

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Immunology

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Where Are We Going?

Any other announcements of upcoming work, events, deadlines, etc?

Three Stages of The Journey

Where Have We Been?

Where Are We Now?

Where Are We Going?

The weekly OHDSI community call is held every Tuesday at 11 am ET.

Everybody is invited!

Links are sent out weekly and available at:
ohdsi.org/community-calls-2025