



European Symposium Recap

OHDSI Community Call
June 11, 2024 • 11 am ET



Upcoming Community Calls

Date	Topic
June 11	European Symposium Review
June 18	Application of LLMs In Evidence Generation Process
June 25	Recent OHDSI Publications



Three Stages of The Journey

Where Have We Been?

Where Are We Now?

Where Are We Going?





OHDSI Shoutouts!



Congratulations to the team of **Giorgio Gandaglia, Francesco Pellegrino, Bertrand De Meulder, Ayman Hijazy, Thomas Abbott, Asieh Golozar, Rossella Nicoletti, Juan Gomez-Rivas, Carl Steinbeisser, Susan Evans-Axelsson, Alberto Briganti, and James N'Dow** on the publication of **Research protocol for an observational health data analysis to assess the applicability of randomized controlled trials focusing on newly diagnosed metastatic prostate cancer using real-world data: PIONEER IMI's "big data for better outcomes" program** in the *International Journal of Surgery Protocols*.

Protocol

INTERNATIONAL JOURNAL OF SURGERY PROTOCOLS

OPEN

Research protocol for an observational health data analysis to assess the applicability of randomized controlled trials focusing on newly diagnosed metastatic prostate cancer using real-world data: PIONEER IMI's "big data for better outcomes" program

Giorgio Gandaglia, MD^{a,*}, Francesco Pellegrino, MD^a, Bertrand De Meulder, MSc^c, Ayman Hijazy, PhD^e, Thomas Abbott, PhD, MBA^d, Asieh Golozar, PhD^a, Rossella Nicoletti, MD^b, Juan Gomez-Rivas, PhD^f, Carl Steinbeisser, MSc^d, Susan Evans-Axelsson, MSc^b, Alberto Briganti, PhD^a, James N'Dow, MD^g

Background: Metastatic prostate cancer (PCa) constitutes ~5% of all new PCa diagnoses in Western countries. For most cases, primary consideration should be given to systemic therapies as the first-line approach based on evidence from randomized controlled trials (RCTs). Despite the importance of RCTs as the pinnacle of evidence in modern medicine, concerns have been raised about their applicability to real-life scenarios. These trials often feature participants who are younger with better performance statuses and prognoses compared to their real-world counterparts. The PIONEER project falls under the Innovative Medicine Initiative's (IMI) "Big Data for Better Outcomes" initiative, aimed at revolutionizing PCa care in Europe. The central focus lies in improving cancer-related outcomes, enhancing health system efficiency, and elevating the quality of health and social care. This study endeavours to evaluate the generalizability of RCT findings concerning newly diagnosed metastatic PCa.

Methods: A systematic review of the literature will be conducted to compile patient characteristics from RCTs addressing this subject within the past decade. To create a real-world benchmark, patients with recently diagnosed metastatic PCa from a network of population-based databases will serve as a comparison group. The objective is to assess the applicability of RCT results in two ways. First, a comparison will be made between the characteristics of patients with newly diagnosed metastatic PCa enrolled in RCTs and those with the same condition included in our databases which might represent the real-world setting. Second, an evaluation will be undertaken to determine the proportion of real-world patients with newly diagnosed metastatic PCa who meet the criteria for RCT enrolment. This study will rely on extensive observational data, primarily sourced from population-based registries, electronic health records, and insurance claims data. The study cohort is established upon routinely gathered healthcare data, meticulously mapped to the Observational Medical Outcomes Partnership Common Data Model.

Keywords: Metastatic prostate cancer, prostatic cancer, randomized controlled trials

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OHDSI Shoutouts!



Congratulations to the team of **Maria A Rujano, Jan-Willem Boiten, Christian Ohmann, Steve Canham, Sergio Contrino, Romain David, Jonathan Ewbank, Claudia Filippone, Claire Connellan, Ilse Custers, Rick van Nuland, Michaela Th Mayrhofer, Petr Holub, Eva García Álvarez, Emmanuel Bacry, Nigel Hughes, Mallory A Freeberg, Birgit Schaffhauser, Harald Wagener, Alex Sánchez-Pla, Guido Bertolini, Maria Panagiotopoulou** on the publication of **Sharing sensitive data in life sciences: an overview of centralized and federated approaches in *Briefings in Bioinformatics***.



Briefings in Bioinformatics, 2024, 25(4), bbae262
<https://doi.org/10.1093/bib/bbae262>
Review

Sharing sensitive data in life sciences: an overview of centralized and federated approaches

Maria A. Rujano¹, Jan-Willem Boiten², Christian Ohmann¹, Steve Canham¹, Sergio Contrino¹, Romain David³, Jonathan Ewbank³, Claudia Filippone³, Claire Connellan³, Ilse Custers², Rick van Nuland², Michaela Th. Mayrhofer⁴, Petr Holub⁴, Eva García Álvarez⁴, Emmanuel Bacry⁵, Nigel Hughes⁶, Mallory A. Freeberg⁷, Birgit Schaffhauser⁸, Harald Wagener⁹, Alex Sánchez-Pla¹⁰, Guido Bertolini¹¹, Maria Panagiotopoulou^{12*}

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Maria A. Rujano, PhD in Medical Sciences from the University of Groningen, serves as a Project Manager at ECRIN contributing to EU initiatives for healthcare data research. With expertise in cell and neurodevelopmental biology, she has worked at prestigious research centres, including Institute Curie and Institute Pasteur.

Jan-Willem Boiten, PhD in Chemistry is a Senior Program Manager at Lygature. With over 20 years of experience in multicentre collaborations across life sciences, he is coordinating large-scale biomedical data infrastructure programs in the Netherlands as well as at the European level.

Christian Ohmann has a PhD in Mathematics, an interim examination in medicine and a habilitation in the field of 'Theoretical Surgery'. He was the head of the Coordination Centre for Clinical Trials (KKS) at the Medical Faculty of the Heinrich Heine University Dusseldorf, Germany (1999-2014) and currently consults ECRIN on clinical trial data sharing and chairs ECRIN's Network Committee.

Steve Canham, a senior data manager at ECRIN, brings 18 years of expertise in clinical trial data systems and management. Formerly, he led the IT team at the Institute of Cancer Research, London (2002-11).

Sergio Contrino is the Head of Data Projects at ECRIN. An Electronics Engineer by training, he has previously worked as a senior software developer at the University of Cambridge, Genetics department, and at the European Bioinformatics Institute (EBI).

Romain David, PhD in Oceanography and Data Mining, serves as a Research Fellow and Data Steward at ERINHA. With 20 years of expertise in environmental information systems, he specializes in data mining, graph approaches and FAIR-compliant data management. He contributes as a co-chair to Research Data Alliance (RDA) Interest Groups (e.g. sensitive data).

Jonathan Ewbank joined ERINHA as Director General in 2021, after 25 years as a group leader at Centre of Immunology of Marseille-Luminy (France).

Claudia Filippone is a virologist working as a senior Scientific Programme Manager at ERINHA. Her research experience focuses on viral emergence and zoonoses, both in Europe and Africa.

Claire Connellan, a European Project Manager at ERINHA, focuses on the Integrated Services of Infectious Disease Outbreak Research (ISIDORE) project, that aims to enhance pandemic preparedness. With expertise in project management and policy development, she holds an MA in International Peace and Security from King's College London.

Ilse Custers is a pharmacologist (VU Amsterdam) and health economist (Pompeu Fabra University) by training. She is currently working as a Program Manager in Lygature managing projects that build infrastructure for health and genomic data sharing.



OHDSI Shoutouts!



Congratulations to the team of **Pedro Mateus, Justine Moonen, Magdalena Beran, Eva Jaarsma, Sophie M van der Landen, Joost Heuvelink, Mahlet Birhanu, Alexander Harms, Esther Bron, Frank J Wolters, Davy Cats, Hailiang Mei, Julie Oomens, Willemijn Jansen, Miranda T Schram, Andre Dekker, and Inigo Bermejo** on the publication of **Data harmonization and federated learning for multi-cohort dementia research using the OMOP common data model: A Netherlands consortium of dementia cohorts case study** in the *Journal of Biomedical Informatics*.

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Original Research

Data harmonization and federated learning for multi-cohort dementia research using the OMOP common data model: A Netherlands consortium of dementia cohorts case study

Pedro Mateus^{a,*}, Justine Moonen^{b,c}, Magdalena Beran^{d,e}, Eva Jaarsma^{f,g}, Sophie M. van der Landen^{b,c}, Joost Heuvelink^b, Mahlet Birhanu^h, Alexander G.J. Harms^h, Esther Bron^h, Frank J. Woltersⁱ, Davy Cats^j, Hailiang Mei^j, Julie Oomens^k, Willemijn Jansen^k, Miranda T. Schram^{l,m,n,o}, Andre Dekker^a, Inigo Bermejo^a

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ABSTRACT

Background: Establishing collaborations between cohort studies has been fundamental for progress in health research. However, such collaborations are hampered by heterogeneous data representations across cohorts and legal constraints to data sharing. The first arises from a lack of consensus in standards of data collection and representation across cohort studies and is usually tackled by applying data harmonization processes. The second is increasingly important due to raised awareness for privacy protection and stricter regulations, such as the GDPR. Federated learning has emerged as a privacy-preserving alternative to transferring data between institutions through analyzing data in a decentralized manner.

Methods: In this study, we set up a federated learning infrastructure for a consortium of nine Dutch cohorts with appropriate data available to the etiology of dementia, including an extract, transform, and load (ETL) pipeline for data harmonization. Additionally, we assessed the challenges of transforming and standardizing cohort data using the Observational Medical Outcomes Partnership (OMOP) common data model (CDM) and evaluated our tool in one of the cohorts employing federated algorithms.

Results: We successfully applied our ETL tool and observed a complete coverage of the cohorts' data by the OMOP CDM. The OMOP CDM facilitated the data representation and standardization, but we identified limitations for cohort-specific data fields and in the scope of the vocabularies available. Specific challenges arise in a multi-cohort federated collaboration due to technical constraints in local environments, data heterogeneity, and lack of direct access to the data.



OHDSI Shoutouts!



Congratulations to the team of **Felix N Wirth, Hammam Abu Attieh, and Fabian Prasser** on the publication of **OHDSI-compliance: a set of document templates facilitating the implementation and operation of a software stack for real-world evidence generation** in *Frontiers in Medicine*.

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OHDSI-compliance: a set of document templates facilitating the implementation and operation of a software stack for real-world evidence generation

Felix N. Wirth, Hammam Abu Attieh and Fabian Prasser*

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Introduction: The open-source software offered by the Observational Health Data Science and Informatics (OHDSI) collective, including the OMOP-CDM, serves as a major backbone for many real-world evidence networks and distributed health data analytics platforms. While container technology has significantly simplified deployments from a technical perspective, regulatory compliance can remain a major hurdle for the setup and operation of such platforms. In this paper, we present OHDSI-Compliance, a comprehensive set of document templates designed to streamline the data protection and information security-related documentation and coordination efforts required to establish OHDSI installations.

Methods: To decide on a set of relevant document templates, we first analyzed the legal requirements and associated guidelines with a focus on the General Data Protection Regulation (GDPR). Moreover, we analyzed the software architecture of a typical OHDSI stack and related its components to the different general types of concepts and documentation identified. Then, we created those documents for a prototypical OHDSI installation, based on the so-called Broadsea package, following relevant guidelines from Germany. Finally, we generalized the documents by introducing placeholders and options at places where individual institution-specific content will be needed.



OHDSI Shoutouts!



Congratulations to the team of **Shahim Essaid, Jeff Andre, Ian M Brooks, Katherine H Hohman, Madelyne Hull, Sandra L Jackson, Michael G Kahn, Emily M Kraus, Neha Mandadi, Amanda K Martinez, Joyce Y Mui, Bob Zambarano, and Andrey Soares** on the publication of **MENDS-on-FHIR: leveraging the OMOP common data model and FHIR standards for national chronic disease surveillance in JAMIA Open.**

JAMIA Open, 2024, 7(2), o0ae045
<https://doi.org/10.1093/jamiaopen/o0ae045>
Research and Applications



Research and Applications

MENDS-on-FHIR: leveraging the OMOP common data model and FHIR standards for national chronic disease surveillance

Shahim Essaid , MD¹, Jeff Andre , MS², Ian M. Brooks , PhD^{1,3}, Katherine H. Hohman , DrPH⁴, Madelyne Hull , MPH³, Sandra L. Jackson , PhD⁵, Michael G. Kahn , MD, PhD^{*,1,3}, Emily M. Kraus , PhD^{6,7}, Neha Mandadi , MS^{1,3}, Amanda K. Martinez , MPH, MSN, RN⁴, Joyce Y. Mui , MPM^{1,3}, Bob Zambarano , PhD², Andrey Soares , PhD⁸

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Abstract

Objectives: The Multi-State EHR-Based Network for Disease Surveillance (MENDS) is a population-based chronic disease surveillance distributed data network that uses institution-specific extraction-transformation-load (ETL) routines. MENDS-on-FHIR examined using Health Language Seven's Fast Healthcare Interoperability Resources (HL7[®] FHIR[®]) and US Core Implementation Guide (US Core IG) compliant resources derived from the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) to create a standards-based ETL pipeline.

Materials and Methods: The input data source was a research data warehouse containing clinical and administrative data in OMOP CDM Version 5.3 format. OMOP-to-FHIR transformations, using a unique JavaScript Object Notation (JSON)-to-JSON transformation language called Whistle, created FHIR R4 V4.0.1/US Core IG V4.0.0 conformant resources that were stored in a local FHIR server. A REST-based Bulk FHIR \$export request extracted FHIR resources to populate a local MENDS database.

Results: Eleven OMOP tables were used to create 10 FHIR/US Core compliant resource types. A total of 1.13 trillion resources were extracted and inserted into the MENDS repository. A very low rate of non-compliant resources was observed.

Discussion: OMOP-to-FHIR transformation results passed validation with less than a 1% non-compliance rate. These standards-compliant FHIR resources provided standardized data elements required by the MENDS surveillance use case. The Bulk FHIR application programming interface (API) enabled population-level data exchange using interoperable FHIR resources. The OMOP-to-FHIR transformation pipeline creates a FHIR interface for accessing OMOP data.

Conclusion: MENDS-on-FHIR successfully replaced custom ETL with standards-based interoperable FHIR resources using Bulk FHIR. The OMOP-to-FHIR transformations provide an alternative mechanism for sharing OMOP data.



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	Common Data Model Vocabulary Subgroup
Tuesday	12 pm	Generative AI and Analytics
Tuesday	3 pm	OMOP CDM Oncology Outreach/Research Subgroup
Wednesday	7 am	Medical Imaging
Wednesday	9 am	Patient-Level Prediction
Wednesday	12 pm	Health Equity
Wednesday	2 pm	Natural Language Processing
Wednesday	4 pm	Joint Vulcan/OHDSI meeting
Thursday	9:30 am	Network Data Quality
Thursday	10:30 am	Evidence Network
Thursday	12 pm	Strategus HADES Subgroup
Thursday	6 pm	Eyecare and Vision Research
Friday	9 am	Phenotype Development & Evaluation
Friday	10 am	GIS-Geographic Information System
Friday	10 pm	China Chapter
Monday	9 am	Vaccine Vocabulary
Monday	10 am	Healthcare Systems Interest Group
Monday	11 am	Data Bricks User Group
Monday	2 pm	Electronic Animal Health Records



Collaborator Showcase Deadline: June 21

The deadline to submit your brief report for the 2021 Global Symposium Collaborator Showcase is 8 pm ET on June 21.



ohdsi.org/2024-ohdsi-symposium-collaborator-showcase



Collaborator Showcase Deadline: June 21

The deadline to submit your brief report for the 2021 Global Symposium Collaborator Showcase is 8 pm ET on June 21.

In other words, you have less than:

- 10 days, 9 hours
- 249 hours
- 14,940 minutes



ohdsi.org/2024-ohdsi-symposium-collaborator-showcase



#OHDSI2024 Collaborator Showcase

OHDSI

2024 OHDSI Collaborator Showcase Brief Report Submission Form- Posters, Oral Talks and Software Demonstrations

Thank you for your interest in the 2024 OHDSI Collaborators Showcase! We are delighted that you are interested in showcasing your work at this year's symposium showcase, which will take place at the Hyatt Regency Hotel in New Brunswick, New Jersey, USA, October 22-24, 2024.

The deadline to submit your brief report is **Friday, June 21 at 8:00pmET**.

By filling out this form you may choose if you would like to present your work as a poster, an oral talk or a software demonstration (or all three). If a poster or software demo, you will present it during the Collaborator Showcase at the symposium. If an Oral talk, you will present an estimated 7-minute talk at the symposium. Although we strive to accommodate your requested presentation format, it is not guaranteed. If the review committee has selected your work to be presented at this year's showcase, you will be notified via email by Tuesday, August 20, 2024, and the presentation format will be confirmed at that time.

Topics should align with at least one of OHDSI's strategic areas of focus:

- Observational data standards and management
- Open-source analytics development
- Methodological research
- Clinical applications

SUBMISSION INSTRUCTIONS:

A brief report submission template can be found by using the below link: https://docs.google.com/document/d/1GADPitvH1eHXH_W9qB0lg-nv2gAVnloH2c7kCqtWGqk/edit?usp=sharing

The document can be downloaded as a Microsoft Word document by clicking on the link and selecting File->Download As...-> Microsoft Word (.docx).

Each presenting author should upload their document as a PDF. The submission should meet the following guidelines:

The screenshot shows the OHDSI website homepage. The navigation bar includes: Who We Are, Updates & News, Standards, Software Tools, Network Studies, Community Forums, Education, New To OHDSI?, Community Calls, Past Events, Workgroups, 2023 'Our Journal' Annual Report, This Week In OHDSI, Support & Sponsorship, CBER Best Seminars, 2024 Europe Symposium, 2024 Global Symposium (highlighted with an orange circle), Github, YouTube, Twitter, LinkedIn, Newsletters. The main content area features a 'Welcome to OHDSI' section and a '2024 Global Symposium' section. The dropdown menu for '2024 Global Symposium' includes: 2024 Collaborator Showcase Details, 2024 Collaborator Showcase Submission Form (highlighted with an orange circle), 2024 Tutorial Descriptions, 2024 Workgroup Activities, Book Your Sleeping Room, and Frequently Asked Questions.

ohdsi.org/OHDSI2024

Latest OHDSI Newsletter is Available



The Journey Newsletter (June 2024)

The deadline for submitting your brief reports for the 2024 OHDSI Global Symposium Collaborator Showcase is **Friday, June 21 (8 pm ET)**, and we share all the necessary suggestions and key links so that you can be part of another great collaborative activity during #OHDSI2024 Collaborator Showcase. This newsletter also includes recent tutorials and study updates shared in May, community updates, recent publications and plenty more.

[#JoinTheJourney](#)

Videocast: OHDSI2024 Collaborator Showcase



In the latest On The Journey videocast, Patrick Ryan and Craig Sachson focus their attention on the 2024 Global Symposium Collaborator Showcase. They look at the wide breadth of research that the scientific review committee seeks, and why the research presented at the symposium is often not the end of the journey, but a vehicle for collaboration. They also reflect on its significance to the symposium itself. (if video does not appear, please click 'View this email in your browser')



Collaborator Showcase Countdown! Insights & Details To Help Submit Your Research Before The June 21 Deadline

OHDSI's achievements over the last decade would not be possible without the tremendous scientific advancements made by our community members around the world. New research in data standards, methods, open-source development and clinical applications continue driving us forward in our mission to collaboratively generate the evidence that promotes better health decisions and better care.

Our annual collaborator showcase provides our community the opportunity to share their tremendous work, whether it is completed or ongoing. The Global Symposium Collaborator Showcase has received a record number of submissions in each of the last two years, but many still wonder if their interests or current research fit into a showcase submission (hint: it probably does). Patrick Ryan shares thoughts in the video below on what type of research can benefit the community at the Global Symposium.

Publications

Adams WG, Gasman S, Beccia AL, Fuentes L. [The Health Equity Explorer: An open-source resource for distributed health equity visualization and research across common data models](#). J Clin Transl Sci. 2024 Apr 5;8(1):e72. doi: 10.1017/cts.2024.500. PMID: 38690224; PMCID: PMC11058576.

Matacotta JJ, Tran D, Yoon S. [The prevalence of major depressive disorder in people with HIV: Results from the All of Us Research Program](#). HIV Med. 2024 May 7. doi: 10.1111/hiv.13653. Epub ahead of print. PMID: 38715437.

Nguyen PA, Hsu MH, Chang TH, Yang HC, Huang CW, Liao CT, Lu CY, Hsu JC. [Taipei Medical University Clinical Research Database: a collaborative hospital EHR database aligned with international common data standards](#). BMJ Health Care Inform. 2024 May 14;31(1):e100890. doi: 10.1136/bmjhci-2023-100890. PMID: 38749529; PMCID: PMC11097871.

Waltemath D, Beyan O, Cramer K, Dedié A, Gierend K, Gröber P, Inau ET, Michaelis L, Reinecke I, Sedlmayr M, Thun S, Krefting D. [FAIRe Gesundheitsdaten im nationalen und internationalen Datenraum \[FAIR health data in the national and international data space\]](#). Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2024 May 15. German. doi: 10.1007/s00103-024-03884-8. Epub ahead of print. PMID: 38750239.

Burkard T, López-Güell K, Gorbachev A, Bellas L, Jödicke AM, Burn E, de Ridder M, Mosseveld M, Gratton J, Seager S, Vojinovic D, Mayer MA, Ramírez-Anguita JM, Machín AL, Oja M, Kolde R, Bonadt K, Prieto-Alhambra D, Reich C, Català M. [Calculating daily dose in the Observational Medical Outcomes Partnership Common Data Model](#). Pharmacoepidemiol Drug Saf. 2024 Jun;33(6):e5809. doi: 10.1002/pds.5809. PMID: 38773798.

Fridgeirsson EA, Williams R, Rijnbeek P, Suchard MA, Reips JM. [Comparing penalization methods for linear models on large observational health data](#). J Am Med Inform Assoc. 2024 May 20;ocae109. doi: 10.1093/jamia/ocae109. Epub ahead of print. PMID: 38767857.

Community Updates

Where Have We Been?

• Four open-source development leaders provided background information and brief live demonstrations on tools that can aid our community in observational healthcare research earlier this month. Find those and others on [our open-source tutorial page](#).

• **George Hripscak** delivered the latest CBER BEST Seminar Series presentation on [Diagnosing Covariate Imbalance in Small-Cohort Studies](#). You can [watch that video](#) and [check out his slides](#) now.

• Understudied women's health conditions like endometriosis & polycystic ovary syndrome (PCOS) require greater research. [OHDSI collaborators joined with faculty and trainees at Columbia University](#) to advance women's health, empower women & support shared decision-making with their providers.

Where Are We Now?

• Submissions for the 2024 OHDSI Global Symposium Collaborator Showcase are due June 21 at 8 pm ET. Information about the Collaborator Showcase [is available here](#), and the submission link [can be found here](#).

• The 2024 Europe Symposium was held June 1-3 in Rotterdam, Neth., and its theme was "Scaling up reliable evidence across Europe." Videos and posters from the event will be posted on the OHDSI website and shared via OHDSI's [LinkedIn](#), [Twitter/X](#) and [Instagram](#) feeds when available.

• The next edition of the CBER BEST Seminar Series will be held Wednesday, June 26, at 11 am ET. **Jenna Wong**, Assistant Professor in the Department of Population Medicine at Harvard Medical School and Harvard Pilgrim Health Care Institute, will lead a session on [Applying Machine Learning in Distributed Networks to Support Activities for Post-Market Surveillance of Medical Products: Opportunities, Challenges, and Considerations](#). The meeting link and full schedule for the CBER BEST Seminar Series, including past presentations, [is available here](#). The abstract from that talk is posted below.



Next CBER Best Seminar: June 26

Topic: Applying Machine Learning in Distributed Networks to Support Activities for Post-Market Surveillance of Medical Products: Opportunities, Challenges, and Considerations

Presenter: Jenna Wong, Assistant Professor in the Department of Population Medicine at Harvard Medical School and Harvard Pilgrim Health Care Institute

Logistics: 11 am – 12 pm EST, Zoom webinar



ohdsi.org/cber-best-seminar-series



CBER Best Seminar Homepage

CBER BEST Seminar Series

The [CBER BEST Initiative](#) Seminar Series is designed to share and discuss recent research of relevance to ongoing and future surveillance activities of CBER regulated products, namely biologics. The series focuses on safety and effectiveness of biologics including vaccines, blood components, blood-derived products, tissues and advanced therapies. The seminars will provide information on characteristics of biologics, required infrastructure, study designs, and analytic methods utilized for pharmacovigilance and pharmacoepidemiologic studies of biologics. They will also cover information regarding potential data sources, informatics challenges and requirements, utilization of real-world data and evidence, and risk-benefit analysis for biologic products. The length of each session may vary, and the presenters will be invited from outside FDA.



Below you will find details of upcoming CBER BEST seminars, including virtual links that will be open to anybody who wishes to attend. Speakers who give their consent to be recorded will also have their presentations included on this page; you can find those sessions below the list of upcoming speakers.

Upcoming Seminars

+ June 26, 2024 (11 am) - Jenna Wong, Harvard University

+ July 17, 2024 (11 am) - Yonas Ghebremichael-Weldeselassie, Warwick Medical School

Previous Seminars

+ May 22, 2024 - George Hripcsak, Columbia University

+ April 17, 2024 - Yong Chen, University of Pennsylvania

+ Jan. 17, 2024 - Anna Ostropolets, Odysseus Data Services

+ Dec. 6, 2023 - Jenny Sun, Pfizer

ohdsi.org/cber-best-seminar-series



OHDSI Evidence Network Study

Clair Blacketer

Lead, CDM Workgroup

Lead, Network Data Quality Workgroup



Why are we here?

THE LANCET

ARTICLES | VOLUME 394, ISSUE 10211, P1816-1826, NOVEMBER 16, 2019

[Download Full Issue](#)

Comprehensive comparative effectiveness and safety of first-line antihypertensive drug classes: a systematic, multinational, large-scale analysis

Prof Marc A Suchard, MD • Martijn J Schuemie, PhD • Prof Harlan M Krumholz, MD • Seng Cha RuiJun Chen, MD • Nicole Pratt, PhD • et al. [Show all authors](#)

Published: October 24, 2019 • DOI: [https://doi.org/10.1016/S0140-6736\(19\)32317-7](https://doi.org/10.1016/S0140-6736(19)32317-7) [Check for updates](#)

thebmj covid-19 Research Education News & Views Campaigns Jobs

Research » Special paper

Characterising the background incidence rates of adverse events of special interest for covid-19 vaccines in eight countries: multinational network cohort study

BMJ 2021 ; 373 doi: <https://doi.org/10.1136/bmj.n1435> (Published 14 June 2021)
Cite this as: BMJ 2021;373:n1435

[Read our latest coverage of the coronavirus pandemic](#)

THE LANCET
Rheumatology

ARTICLES | VOLUME 2, ISSUE 11, E698-E711, NOVEMBER 2020 [Download Full Issue](#)

Risk of hydroxychloroquine alone and in combination with azithromycin in the treatment of rheumatoid arthritis: a multinational, retrospective study

Jennifer C E Lane, MRCS † • James Weaver, MSc † • Kristin Kostka, MPH • Talita Duarte-Salles, PhD • Maria Tereza F Abrahao, PhD • Heba Alghoul, MD • et al. [Show all authors](#) • [Show footnotes](#)

Open Access • Published: August 21, 2020 • DOI: [https://doi.org/10.1016/S2665-9913\(20\)30276-9](https://doi.org/10.1016/S2665-9913(20)30276-9) [Check for updates](#)

...to collaboratively generate evidence that promotes better health decisions and better care.



Save our Sisyphus Challenge

Amongst people with psoriasis, does exposure to Risankizumab increase the risk of cerebrovascular events while on treatment relative to other biologic therapies?

Lead: Zenas Yiu

Characterization: incidence of progressive multifocal leukoencephalopathy (PML) during Multiple Sclerosis (MS) biologic exposure

Lead: Thamir Alshammary

*OHDSI Save Our Sisyphus Challenge
7th March 2023*

Population Estimation: Comparative safety:

Amongst people with psoriasis, does exposure to Risankizumab increase the risk of venous thromboembolism while on treatment relative to other biologic therapies?

Zenas Yiu
Clinical Senior Lecturer in Dermatology
University of Manchester

Introductory Video

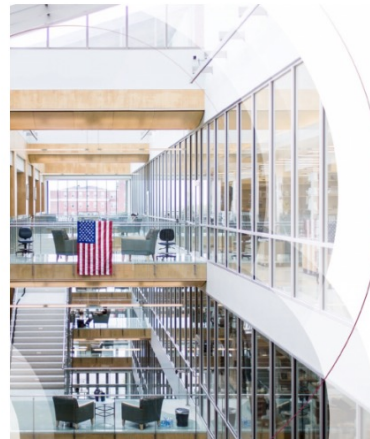
Introductory Slides

MS Teams Channel

GitHub Repo

Intravitreal Anti-VEGF and Kidney Failure

Lead: Cindy Cai



Wilmer Eye Institute
Johns Hopkins Medicine

OHDSI SOS Challenge: Intravitreal Anti-VEGF and Kidney Failure

Cindy X. Cai, MD
The Jonathan and Marcia Javitt Rising Professor
Assistant Professor of Ophthalmology
Retina Division, The Wilmer Eye Institute
Johns Hopkins University School of Medicine

3/7/2023

Introductory Video

Introductory Slides

MS Teams Channel

GitHub Repo

Is fluoroquinolone use really associated with the development of aortic aneurysms

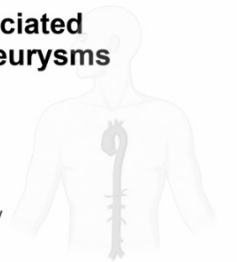
Leads: Jack Janetzki, Jung Ho Kim, Seonji Kim, Jung Ah Lee, Nicole Pratt, Seng Chan You,

Is fluoroquinolone use really associated with the development of aortic aneurysms and aortic dissections?

OHDSI Save Our Sisyphus Challenge 2023

Initial collaborators

Seng Chan You, Seonji Kim, Jung Ho Kim, Jung Ah Lee - Yonsei University
Jack Janetzki, Nicole Pratt - University of South Australia



YONSEI
UNIVERSITY

University of
South Australia

Introductory Video

Introductory Slides

MS Teams Channel

GitHub Repo



Inaugural Data Sources of the OHDSI Evidence Network Pilot

Ajou University • Ajou University
Casa di Cura Igea • Casa di Cura Igea
Clinical Center of Montenegro • Clinical Center of Montenegro
Columbia University Medical Center • Columbia University Medical Center
University College London • UK THIN
IQVIA • Australia EMR
IQVIA • Disease Analyzer France
IQVIA • Disease Analyzer Germany
IQVIA • Japan Claims
IQVIA • Japan HIS
IQVIA • Longitudinal Patient Database (LPD) in Belgium
IQVIA • Longitudinal Patient Database (LPD) in France
IQVIA • Longitudinal Patient Database (LPD) in Italy
IQVIA • Longitudinal Patient Database (LPD) in Spain
IQVIA • OMOP US Hospital Data Master
IQVIA • Pharmedics Plus
IQVIA • UK Medical Research Data EMIS
IQVIA • UK Medical Research Data THIN
IQVIA • US Open Claims
Janssen Research & Development • JMDC
Janssen Research & Development • Merative®
Marketscan® Commercial Claims and Encounters
Janssen Research & Development • Merative®
Marketscan® Medicare Supplemental

Janssen Research & Development • Merative®
Marketscan® Multi-State Medicaid
Janssen Research & Development • Optum's
Clinformatics® Data Mart - Date of Death
Janssen Research & Development • Optum's
Clinformatics® Data Mart - Socio-Economic Status
Janssen Research & Development • Optum's
Longitudinal EHR Repository
Janssen Research & Development • Premier Healthcare
Database
Johns Hopkins University • Johns Hopkins University
National University of Singapore • National University of
Singapore
Northeastern • IQVIA Pharmedics Plus
Organization Name • Data Source Name
Taipei Medical University • Taipei Medical University
Tufts University Medical Center • Tufts University
Medical Center
University of Nebraska Medical Center • University of
Nebraska Medical Center
University of Southern California • Keck Medical Center
US Department of Veteran's Affairs • US Department of
Veteran's Affairs
Yinzhou Bigdata Platform • Yinzhou Bigdata Platform



Learnings from the Pilot

- Keeping the aggregate statistics private is challenging and can be a barrier to open science
- Data owners would like to collaborate to better the quality of their data
- Data owners would like to understand how their data compares to other data sources in the network
- A protocol detailing participation would make it easier to get IRB/governance approval



DIA 2024

GLOBAL ANNUAL MEETING
SAN DIEGO, CA | JUNE 16-20

60TH ANNIVERSARY

CHARTING NEW HORIZONS

OHDSI Meetup

Tuesday, June 18 6pm

Contact

Mui Van Zandt <mui@ohdsi.org>

or

Davera Gabriel <gabriel@ohdsi.org>

for details





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



Charisse Madlock-Brown, PhD
*Associate Professor of Health Informatics,
University of Iowa*

‘Health Disparities Research and Electronic Health
Records: Considerations and Methods’

June 27, 2024, 11am-12pm EST

Virtually via [Zoom](#)

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

TuftsMedicine
Tufts Medical Center



#OHDSI2024 Registration Is Open!

Registration is OPEN for the 2024 OHDSI Global Symposium, which will be held **Oct. 22-24** at the **Hyatt Regency Hotel in New Brunswick, N.J., USA.**

Tuesday: Tutorials

Wednesday: Plenary/Showcase

Thursday: Workgroup Activities

ohdsi.org/OHDSI2024





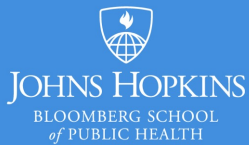
Openings: Postdoctoral Fellow, Johns Hopkins Univ.

PHARMACOEPIDEMIOLOGY POST-DOCTORAL TRAINING PROGRAM

Co-Directors: Caleb Alexander, MD, MS and Jodi Segal, MD, MPH

The **Pharmacoepidemiology Training Program** at the Johns Hopkins Bloomberg School of Public Health (BSPH) is currently **seeking to support postdoctoral fellows**. All supported trainees work with core faculty on existing or newly developed research projects on pharmacoepidemiology, so as to optimize the safe and effective use of medicines to treat heart, lung and blood diseases in the United States. |

Deadline for applications: rolling





Opening: Junior Research Software Engineer, Tufts



INFORMATICS

Research Services

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Data and Safety Monitoring Board (DSMB) Program

Center for Clinical Trials (CCT)

Program Evaluation

Qualitative and Mixed Methods Service

Clinical Trial Design Labs

Dissemination and Implementation (D&I) Core

Science Communications



“Our Informatics team can help you collect and manage research data, develop databases, and identify study participants. We’ll find the best data collection solution for your study. To get started, please submit a request below.”

William Harvey, MD, MSc, FACR
Co-Director, Informatics and Tufts Medical Center CMIO

Overview

We participate in development of a robust institutional informatics infrastructure, enabling research teams to maintain their focus on scientific discovery and analyses rather than on data wrangling. Our infrastructure and support systems are dynamic, to keep pace with the changing and interdependent fields of health informatics, bioinformatics, statistics, and data science; expandable, to accommodate new data types and analytic methods; and scalable, to support efficient and methodologically rigorous multisite/institution research. These defining traits allow us to elucidate novel methods and operational principles, harmonize datasets, and create pipelines for data sharing and analytics.



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 background features a complex geometric composition. A diagonal line runs from the top-left towards the bottom-right. To the left of this line, there are several distinct patterns: a white dot at the top left, a grey semi-circle, a series of concentric blue circles, a pink area with diagonal lines, a solid pink square with a white line pattern, and a grey triangle. The right side of the image is a solid blue field containing the main text.

CDM SURVEY SUB-WORK GROUP



MISSION STATEMENT

The CDM Survey Sub-Workgroup is a collaborative effort to unlock the potential of survey data within the Observational Health Data Sciences and Informatics (OHDSI) framework. We aim to develop a standardized approach for integrating survey data into the OMOP Common Data Model (CDM). This will be achieved through the development of standards, tools, and best practices to transform survey questions and responses into the CDM format. This, in turn, will empower researchers to conduct more robust analyses across diverse datasets, ultimately leading to richer insights and improved health outcomes.

ESTABLISH THE CDM SURVEY SUB-WORKGROUP

- **Key Results**

- Regular meetings held bi-weekly on Mondays at 11:00 AM ET. Meeting recordings, agendas, minutes, and other documentation will be readily available.
- Integration with the OHDSI Workgroup webpage to be established for increased visibility.
- Presentation scheduled for the CDM Workgroup on May 7th to introduce the Sub-Group and its goals.

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.

DEVELOPMENT AND TESTING

- **Activities**

- Develop concrete use cases and showcase the value proposition for integrating survey data into the CDM using the Breast Cancer Risk Prediction Project (BCRPP) and California Teachers Study (CTS) cohorts as examples.

- **Key Results**

- Create two to four detailed use cases to guide the development and application of survey mapping tools.
- Additionally, develop compelling value propositions to encourage the OHDSI community to contribute to the Subgroup or map their own survey data to the CDM.

FIND AND APPLY FOR FUTURE SUPPORT

- **Actions**

- Reach out to participant cohort organizations, OHDSI and elsewhere for funding and individuals to continue the development of CDM survey mapping resources.

- **Key Result**

- Acquire financial and personnel support to carry out the CDM Survey Sub-Workgroup mission.



THANK YOU

Brandy Mapes

Jim Lacey

Katie O'Brien

Magda Meir

Michael Cook

Montse Garcia-Closas

Queenie Ho

Tamara Litwin

Tom Ahearn



Nicole Gerlanc, PhD

Data Analyst Lead, Connect Study
Trans-Divisional Research Program
Division of Cancer Epidemiology and Genetics
National Cancer Institute

Email: nicole.gerlanc@nih.gov

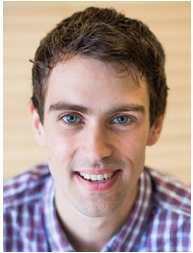


June 11: European Symposium Review



Peter Rijnbeek

Professor of Medical Informatics and Chair of the Department of Medical Informatics, Erasmus MC



Maxim Moinat

Scientific Researcher, Erasmus MC



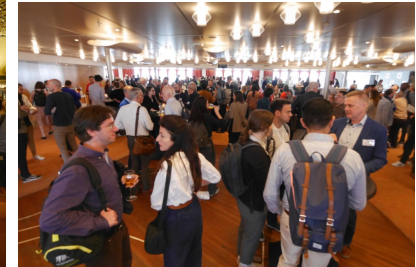
Cesar Barboza Gutierrez

Software Developer, Erasmus MC



Liesbet Peeters

Assistant Professor of Biomedical Data Sciences, UHasselt





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