CDM Workshop, Part 1

OHDSI Community Call
March 8, 2022 • 11 am ET

Future OHDSI Community Calls

Date	Topic
March 15	CDM Workshop (Part 2)
March 22	OHDSI Vocabulary Journey
March 29	Reproducibility
April 5	Name That Result
April 12	OHDSI Coordinating Center
April 19	DARWIN EU
April 26	Open-Source Community

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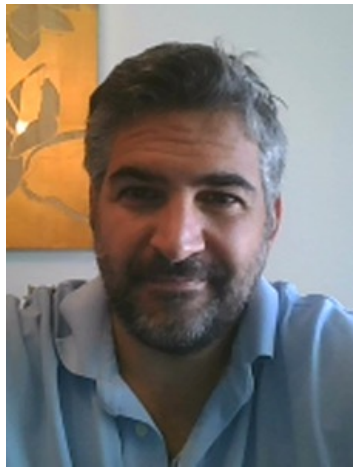
March 15: CDM Workshop, Part 2

Clair Blacketer

Associate Director
Janssen Research & Development



Anthony Molinaro

Manager, Epidemiology Analytics
Janssen Research & Development

Melanie Philofsky

Senior Business Analyst
and Project Manager
Odysseus Data Services, Inc.

Frank DeFalco

Director, Observational Health Data Analytics
Janssen Research & Development

Three Stages of The Journey

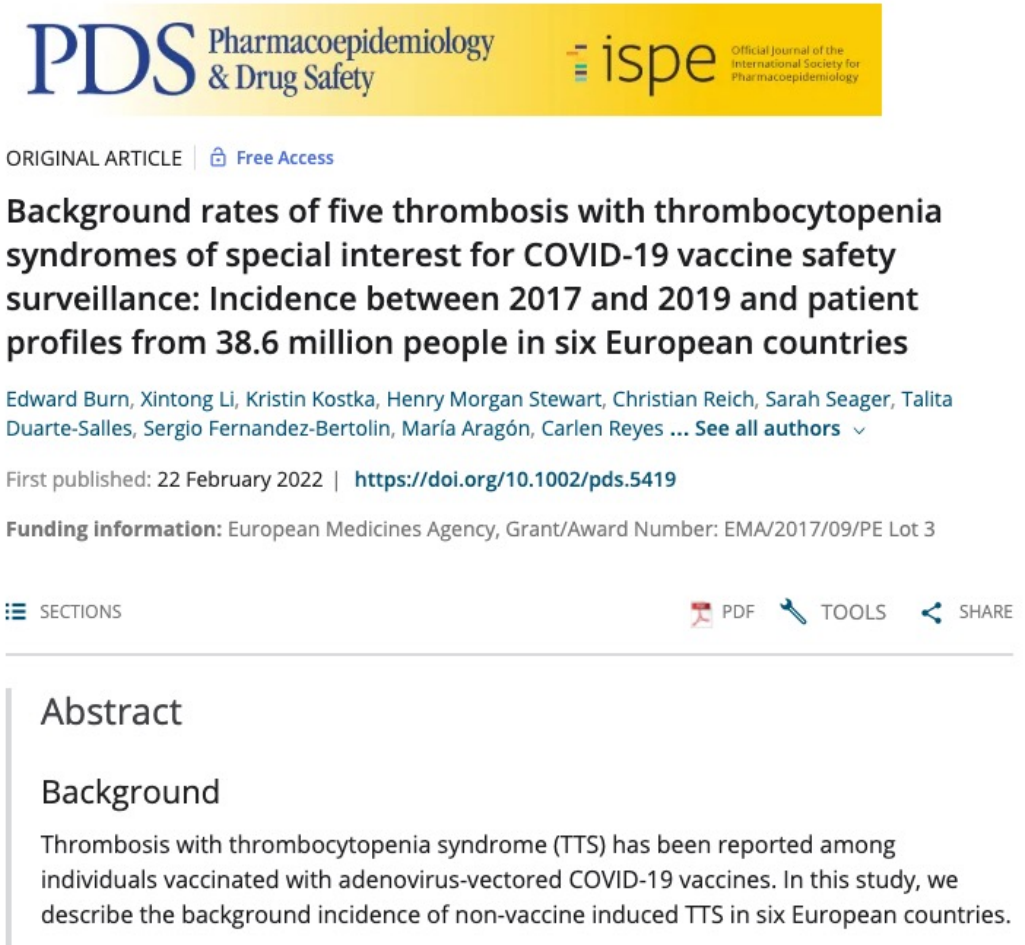
Where Have We Been?

Where Are We Now?

Where Are We Going?

OHDSI Shoutouts!

Congratulations to the team of **Edward Burn, Xintong Li, Kristin Kostka, Henry Morgan Stewart, Christian Reich, Sarah Seager, Talita Duarte-Salles, Sergio Fernandez-Bertolin, María Aragón, Carlen Reyes, Eugenia Martinez-Hernandez, Edelmira Marti, Antonella Delmestri, Katia Verhamme, Peter Rijnbeek, Scott Horban, Daniel Morales, and Daniel Prieto-Alhambra** on the study "**Background rates of five thrombosis with thrombocytopenia syndromes of special interest for COVID-19 vaccine safety surveillance: Incidence between 2017 and 2019 and patient profiles from 38.6 million people in six European countries**" which was recently published in Pharmacoepidemiology and Drug Safety.



PDS Pharmacoepidemiology & Drug Safety — ispe Official Journal of the International Society for Pharmacoepidemiology

ORIGINAL ARTICLE | Free Access

Background rates of five thrombosis with thrombocytopenia syndromes of special interest for COVID-19 vaccine safety surveillance: Incidence between 2017 and 2019 and patient profiles from 38.6 million people in six European countries

Edward Burn, Xintong Li, Kristin Kostka, Henry Morgan Stewart, Christian Reich, Sarah Seager, Talita Duarte-Salles, Sergio Fernandez-Bertolin, María Aragón, Carlen Reyes ... See all authors

First published: 22 February 2022 | https://doi.org/10.1002/pds.5419

Funding information: European Medicines Agency, Grant/Award Number: EMA/2017/09/PE Lot 3

SECTIONS PDF TOOLS SHARE

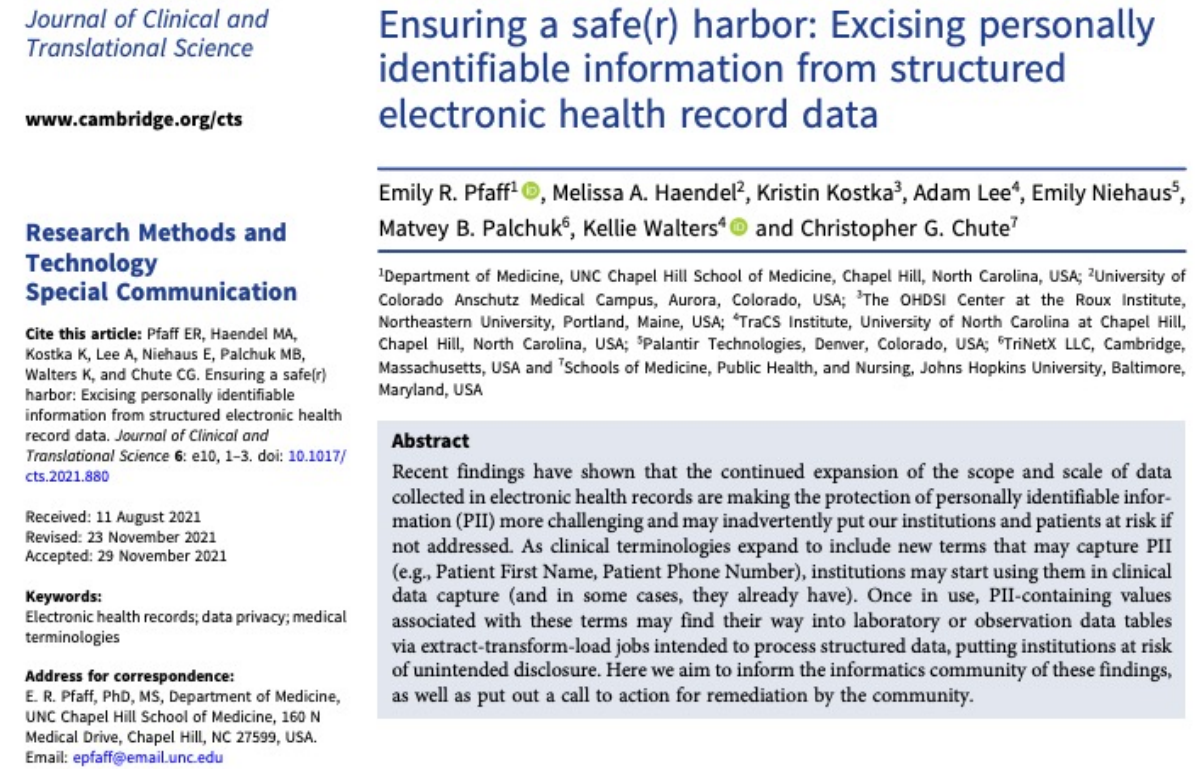
Abstract

Background

Thrombosis with thrombocytopenia syndrome (TTS) has been reported among individuals vaccinated with adenovirus-vectored COVID-19 vaccines. In this study, we describe the background incidence of non-vaccine induced TTS in six European countries.

OHDSI Shoutouts!

Congratulations to the team of **Emily Pfaff, Melissa Haendel, Kristin Kostka, Adam Lee, Emily Niehaus, Matvey Palchuk, Kellie Walters, and Christopher Chute** on the study "**Ensuring a safe(r) harbor: Excising personally identifiable information from structured electronic health record data**" which was recently published in the Journal of Clinical and Translational Science.



Journal of Clinical and Translational Science

www.cambridge.org/cts

Research Methods and Technology Special Communication

Cite this article: Pfaff ER, Haendel MA, Kostka K, Lee A, Niehaus E, Palchuk MB, Walters K, and Chute CG. Ensuring a safe(r) harbor: Excising personally identifiable information from structured electronic health record data. *Journal of Clinical and Translational Science* **6**: e10, 1–3. doi: 10.1017/cts.2021.880

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Keywords:
Electronic health records; data privacy; medical terminologies

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Email: epfaff@email.unc.edu

Ensuring a safe(r) harbor: Excising personally identifiable information from structured electronic health record data

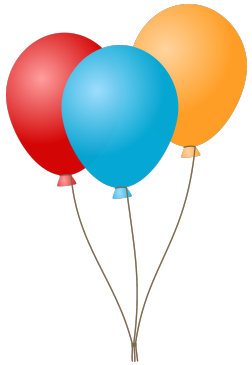
Emily R. Pfaff[1], Melissa A. Haendel[2], Kristin Kostka[3], Adam Lee[4], Emily Niehaus[5], Matvey B. Palchuk[6], Kellie Walters[4] and Christopher G. Chute[7]

[1]Department of Medicine, UNC Chapel Hill School of Medicine, Chapel Hill, North Carolina, USA; [2]University of Colorado Anschutz Medical Campus, Aurora, Colorado, USA; [3]The OHDSI Center at the Roux Institute, Northeastern University, Portland, Maine, USA; [4]TraCS Institute, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA; [5]Palantir Technologies, Denver, Colorado, USA; [6]TriNetX LLC, Cambridge, Massachusetts, USA and [7]Schools of Medicine, Public Health, and Nursing, Johns Hopkins University, Baltimore, Maryland, USA

Abstract

Recent findings have shown that the continued expansion of the scope and scale of data collected in electronic health records are making the protection of personally identifiable information (PII) more challenging and may inadvertently put our institutions and patients at risk if not addressed. As clinical terminologies expand to include new terms that may capture PII (e.g., Patient First Name, Patient Phone Number), institutions may start using them in clinical data capture (and in some cases, they already have). Once in use, PII-containing values associated with these terms may find their way into laboratory or observation data tables via extract-transform-load jobs intended to process structured data, putting institutions at risk of unintended disclosure. Here we aim to inform the informatics community of these findings, as well as put out a call to action for remediation by the community.

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?

2022 OHDSI U.S. Symposium

The 2022 OHDSI U.S. Symposium will be held Oct. 14-16 at the Bethesda North Marriott Hotel & Conference Center in Bethesda, Md. The main symposium day is scheduled to be Friday the 14th, while activities will be held the next two days.

Upcoming Workgroup Calls

Date	Time (ET)	Meeting
Tuesday	12 pm	Common Data Model Vocabulary Subgroup
Wednesday	12 pm	FHIR and OMOP Terminologies Subgroup (Zoom)
Wednesday	2 pm	Natural Language Processing
Wednesday	7 pm	Medical Imaging
Thursday	10 am	Data Quality Dashboard Development
Thursday	1 pm	OMOP CDM Oncology Vocabulary Subgroup
Friday	10 am	Phenotype Development and Evaluation
Friday	11 pm	China Chapter (meeting does not take place in Teams)
Monday	8 am	Early-Stage Researchers
Monday	10 am	Healthcare Systems Special Interest Group

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

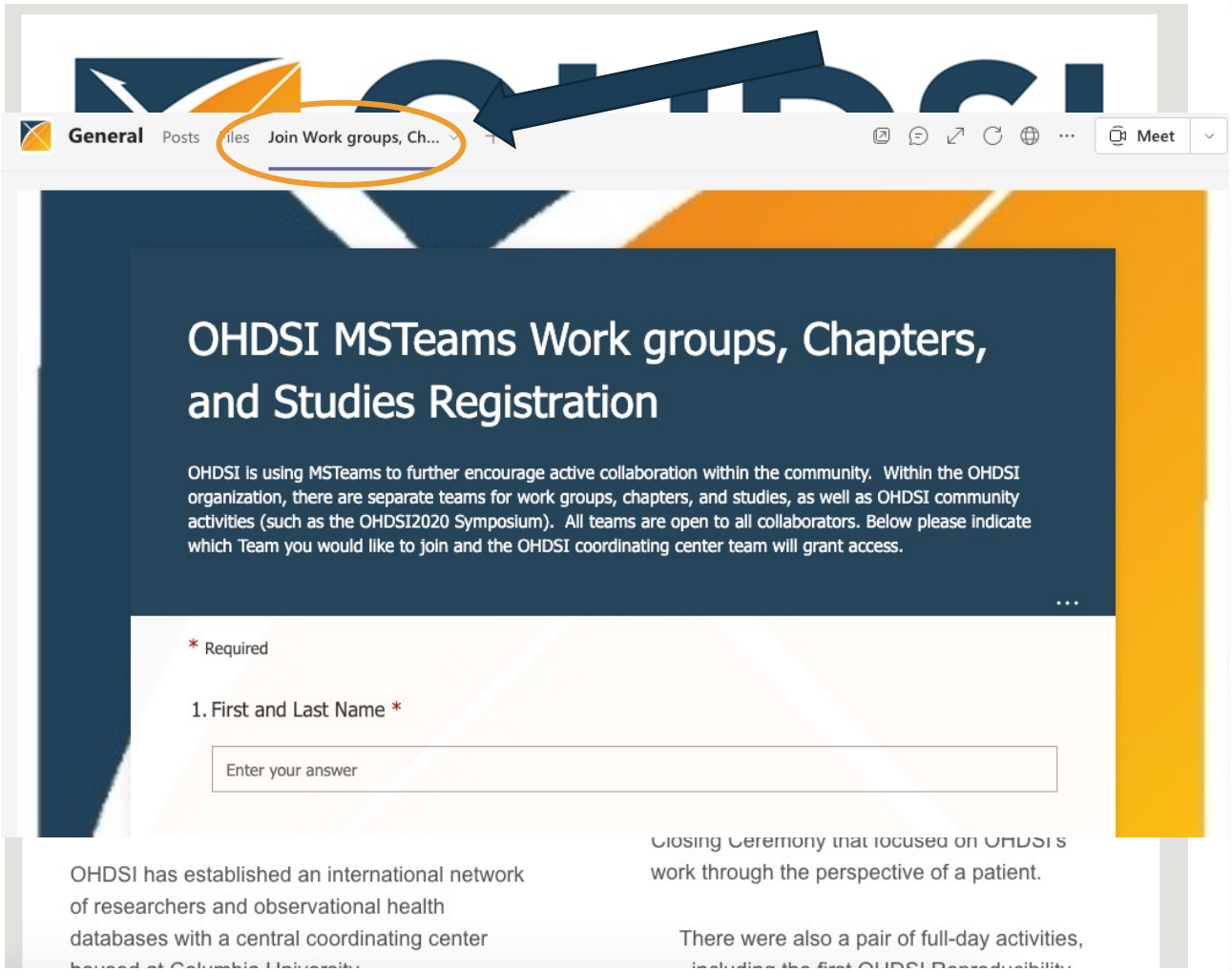
6. Select the chapter(s) you want to join

- [ ] 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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Latest OHDSI Newsletter Is Available

Community Updates

Where Have We Been

• The community engaged in the Phenotype Phebruary initiative, with 15 different collaborators leading 28 conversations about phenotypes. While the calendar has turned, the value in continuing these conversations remains. You can find all threads on developing and evaluating these phenotypes later in the newsletter.

• Leads from most OHDSI workgroups convened for a leadership summit in early February to highlight 2022 Objectives and Key Results (OKRs), and also discuss best practices for leading their respective teams. To learn more and see the 2022 OKRs, please visit our new workgroups page.

Where Are We Now

• The OHDSI community will work with the Erasmus Medical Center to set up the coordinating center for the new DARWIN EU initiative, which was developed by the European Medicines Agency. Read more about this initiative in the newsletter.

• **Clair Blacketer** will lead a two-part CDM 5.4 workshop during our March 8 and 15 community calls. Check out the full March schedule later in this newsletter.

Where Are We Going

• **The 2022 OHDSI Symposium will be held Oct. 14-16**, with the main symposium set for Friday, Oct. 14. More details should be available shortly, but please save those dates.

• The new Open-Source Community Workgroup will host a Developer Conference (DevCon) on Friday, April 22, with plans for several workshops and discussions around new projects and new methods. More information, including how to submit abstracts, will be shared on community calls and our social platforms in March.

OHDSI

The Journey Newsletter (March 2022)

The OHDSI community came together for "Phenotype Phebruary" to both develop and evaluate phenotypes for health outcomes that could be investigated by the community. We reflect on that effort, the recent European Medicines Agency announcement of the DARWIN EU Coordination Center — and how OHDSI fits in that initiative — and discuss plenty more that happened in the community in the latest edition of The Journey! **#JoinTheJourney**

28 Days, 28 Phenotypes

Join The Conversations!

"Phenotype Phebruary" was a community-wide initiative to both develop and evaluate phenotypes for health outcomes that could be investigated by the community. We were so proud to have 15 different members of the community step up and lead forum discussions on phenotypes ranging from Type 2 Diabetes Mellitus and Hypertension to Depression and Delirium.

Check out all the different phenotypes investigated by our community below, visit our Phenotype Phebruary homepage or any of the individual threads, and then add your insights or learn from the great research done by our leads.

March Update Videocast

Patrick Ryan and Craig Sachson discuss why "Phenotype Phebruary" was such a positive community activity, and how it can help OHDSI research initiatives in the future. They also discuss the recent EMA decision to award OHDSI collaborator Erasmus MC with the DARWIN EU contract, and they reflect on the recent Workgroup Leadership Summit.

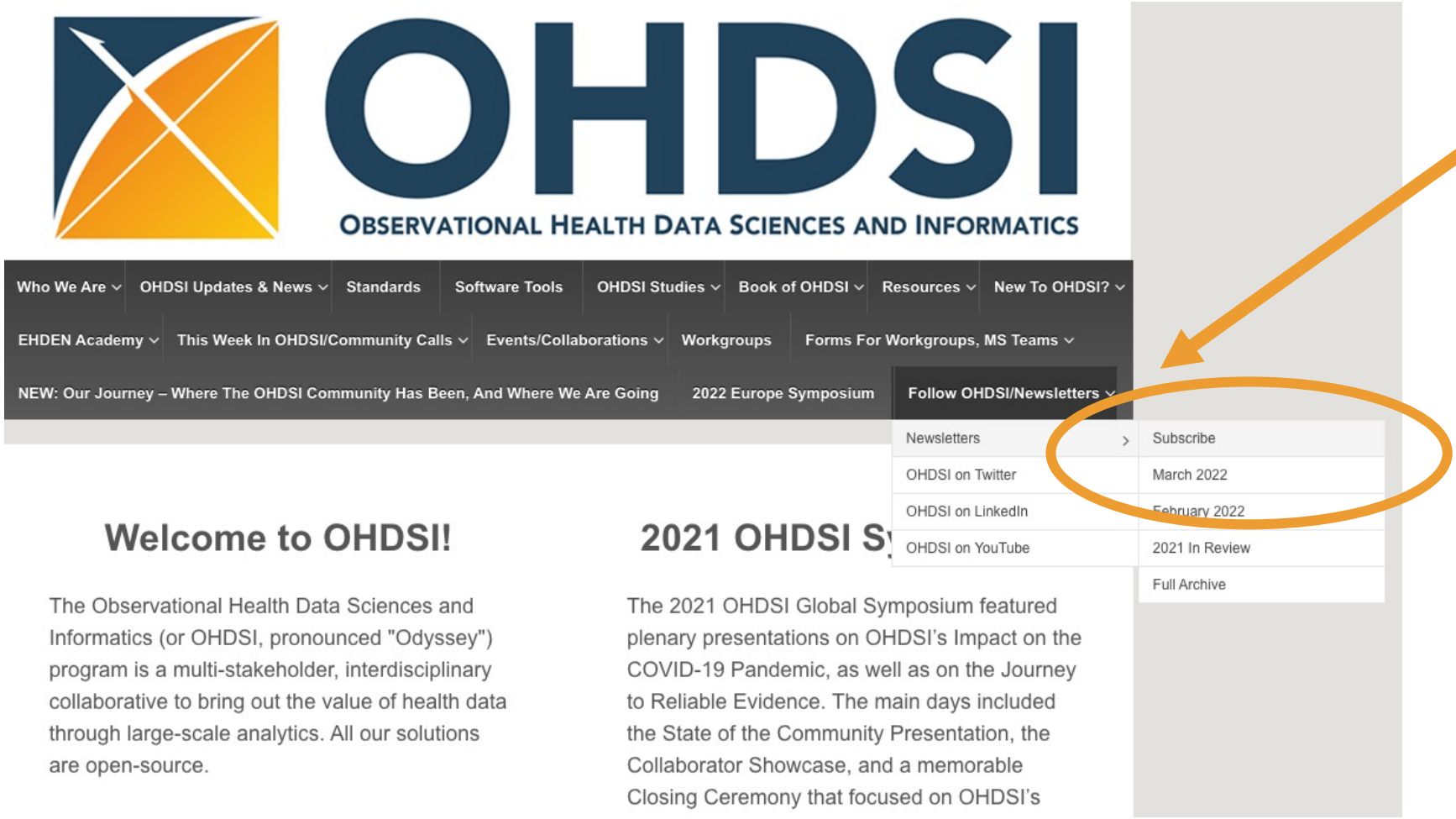
Publications

Lavallee, M., Yu, T., Evans, L. *et al.* Evaluating the performance of temporal pattern discovery: new application using statins and rhabdomyolysis in OMOP databases. *BMC Med Inform Decis Mak* 22, 31 (2022). https://doi.org/10.1186/s12911-022-01765-1

Burn, E., Li, X., Kostka, K., Stewart, H.M., Reich, C., Seager, S., Duarte-Salles, T., Fernandez-Bertolin, S., Aragón, M., Reyes, C., Martinez-Hernandez, E., Marti, E., Delmestri, A., Verhamme, K., Rijnbeek, P., Horban, S., Morales, D.R. and Prieto-Alhambra, D. (2022), Background rates of five thrombosis with thrombocytopenia syndromes of special interest for COVID-19 vaccine safety surveillance: incidence between 2017 and 2019 and patient profiles from 38.6 million people in six European countries. Pharmacoepidemiol Drug Saf. Accepted Author Manuscript. doi.org/10.1002/pds.5419

Cynthia Yang, Jan A Kors, Solomon Ioannou, Luis H John, Aniek F Markus, Alexandros Rekkas, Maria A J de Ridder, Tom M Seinen, Ross D Williams, Peter R Rijnbeek, Trends in the conduct and reporting of clinical prediction model development and validation: a systematic review, *Journal of the American Medical Informatics Association*, 2022;, ocac002, doi.org/10.1093/jamia/ocac002

Latest OHDSI Newsletter Is Available



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Latest OHDSI Newsletter Is Available

Please check out our latest **Collaborator Spotlight,** which features **Maxim Moinat.**

Learn more about this 2021 Titan Award winner, including how track & field helped lead him to work with health data, his work with open-source tools, the Registry WG, DARWIN EU and more!

ohdsi.org/spotlight-maxim-moinat

Next CBER Best Seminar

Topic CBER BEST Seminar Series - Addressing Selection and Confounding Bias in Test-Negative Study Designs for Flu and COVID-19 Monitoring

Description: The test-negative design (TND) has become a standard approach to evaluate vaccine effectiveness against the risk of acquiring infectious diseases such as Influenza, Rotavirus, Dengue fever and more recently COVID-19 in real world settings. Despite the TND's potential to reduce unobserved differences in healthcare seeking behavior (HSB) between vaccinated and unvaccinated subjects, substantial variability in unobserved HSB may remain among study participants. As latent HSB is likely also a strong predictor of selection into the TND sample, confounding bias of the vaccine's causal effect by latent HSB may be induced by collider stratification bias resulting from the TND.

Speakers

Dr. Eric Tchetgen Tchetgen

Luddy Family President's Distinguished Professor @Wharton School of the University of Pennsylvania

Eric J. Tchetgen Tchetgen is the Luddy Family President's Distinguished Professor at the Wharton School of the University of Pennsylvania. Professor Tchetgen Tchetgen comes to the University of Pennsylvania from Harvard University, where he has served since 2008 as Professor of Biostatistics and Epidemiologic Methods with joint appointments in the departments of Biostatistics and Epidemiology at the T.H. Chan School of Public Health. He researches infectious diseases, including HIV/AIDS, and the role of genetic and social factors in the patterns, causes, and effects of public health. Professor Tchetgen Tchetgen has received grants from the National Institutes of Health and the Centers for Disease Control. He completed his Ph.D. in Biostatistics at Harvard University in 2006 under the supervision of Professor James M. Robins. He received his B.S. in Electrical Engineering from Yale University in 1999.

Wed., April 27, 11 am ET

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.

Link on Community Calls page

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.

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Today's Focus: CDM Workshop, Part 1

Clair Blacketer

Associate Director
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Kristin Kostka

Director of the OHDSI Center
Roux Institute, Northeastern University

Frank DeFalco

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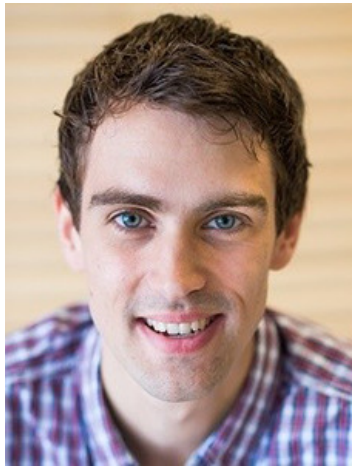

Maxim Moinat

Data Engineer/Software Developer
The Hyve

Dev Con, OHDSI Dashboard

Paul Nagy

Program Director for Graduate Training in Biomedical Informatics and Data Science, Deputy Director of the Johns Hopkins Medicine Technology Innovation Center