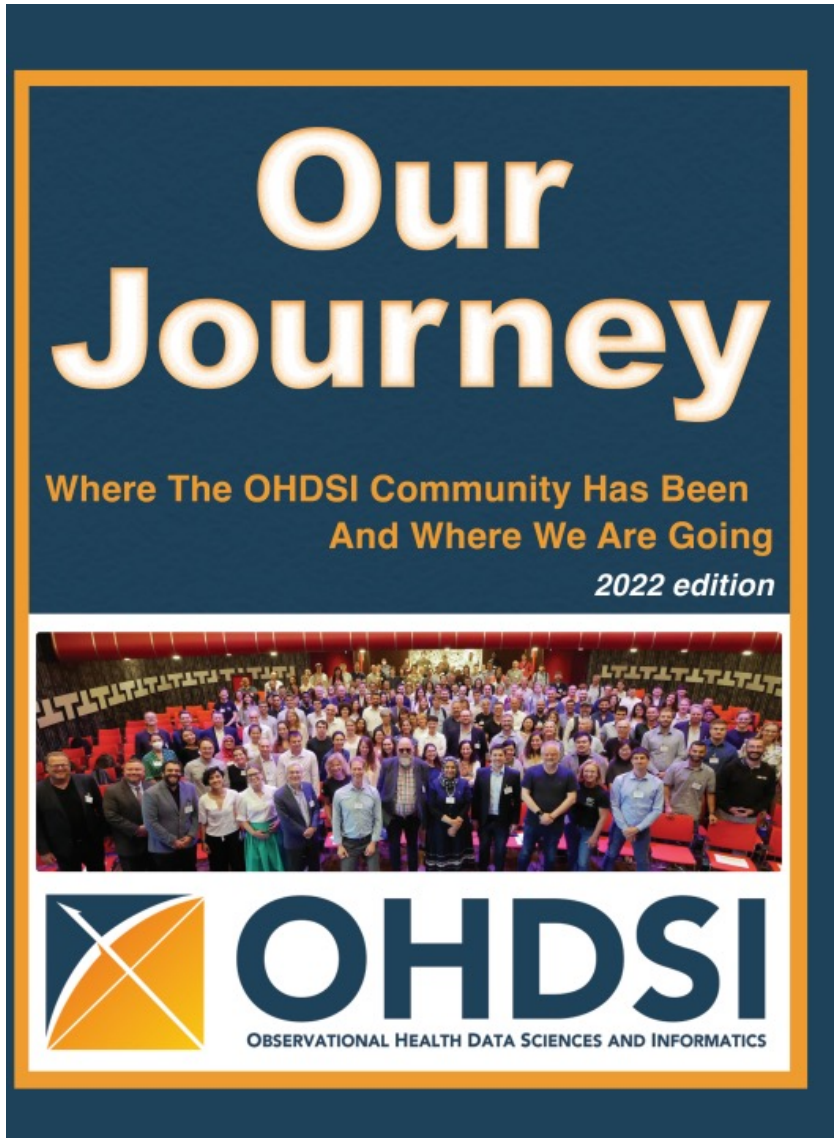
OHDSI 2022
State of the Community

George Hripcsak MD MS

Director, Columbia University OHDSI Coordinating Center
Professor and Chair of Biomedical Informatics
Columbia University Irving Medical Center
NewYork-Presbyterian Hospital

Welcome!

OHDSI: Our Journey



To improve health by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care.

Table Of Contents

We thank the FDA for their generous support of the 2022 OHDSI symposium through the FDA SCIENTIFIC CONFERENCE GRANT PROGRAM (R13FD006972)

Thank you OHDSI Scientific Review Committee

- Thamir Alshammari
- Nsikak Akpakpan
- Juan Banda
- Maytal Bivas-Benita
- Tiffany Callahan
- Adrien Coulet
- Jon Duke
- Leanne Goldstein
- Asieh Golozar
- Kevin Haynes
- Kristin Kostka
- Christophe Lambert
- Rupa Makadia
- Paul Nagy
- Melanie Philofsky
- Jose Posada
- Hanieh Razzaghi
- Jenna Reps
- Patrick Ryan
- Sarah Seager
- Azza Shoaibi
- Joel Swerdel
- Mui Van Zandt
- Rohit Vashisht
- Andrew Williams
- Chen Yanover
- Seng Chan You

Thank you to those who made today happen

- Elisse Katzman
- Craig Sachson
- Jody-Ann McLeggon
- Ann Marshak
- Anita Barrett
- Sofia Loren-Ellis-Chin
- Tiffany Callahan
- Kanchan Chaudhari
- Undina Gilldottir
- Jungmi Han
- Elise Minto
- Anna Ostropolets
- Harry Reyes
- Tony Sun
- Linying Zhang
- Lee Evans
- James Wiggins, AWS
- Mui Van Zandt, Iqvia
- OHDSI Steering Workgroup

OHDSI's mission

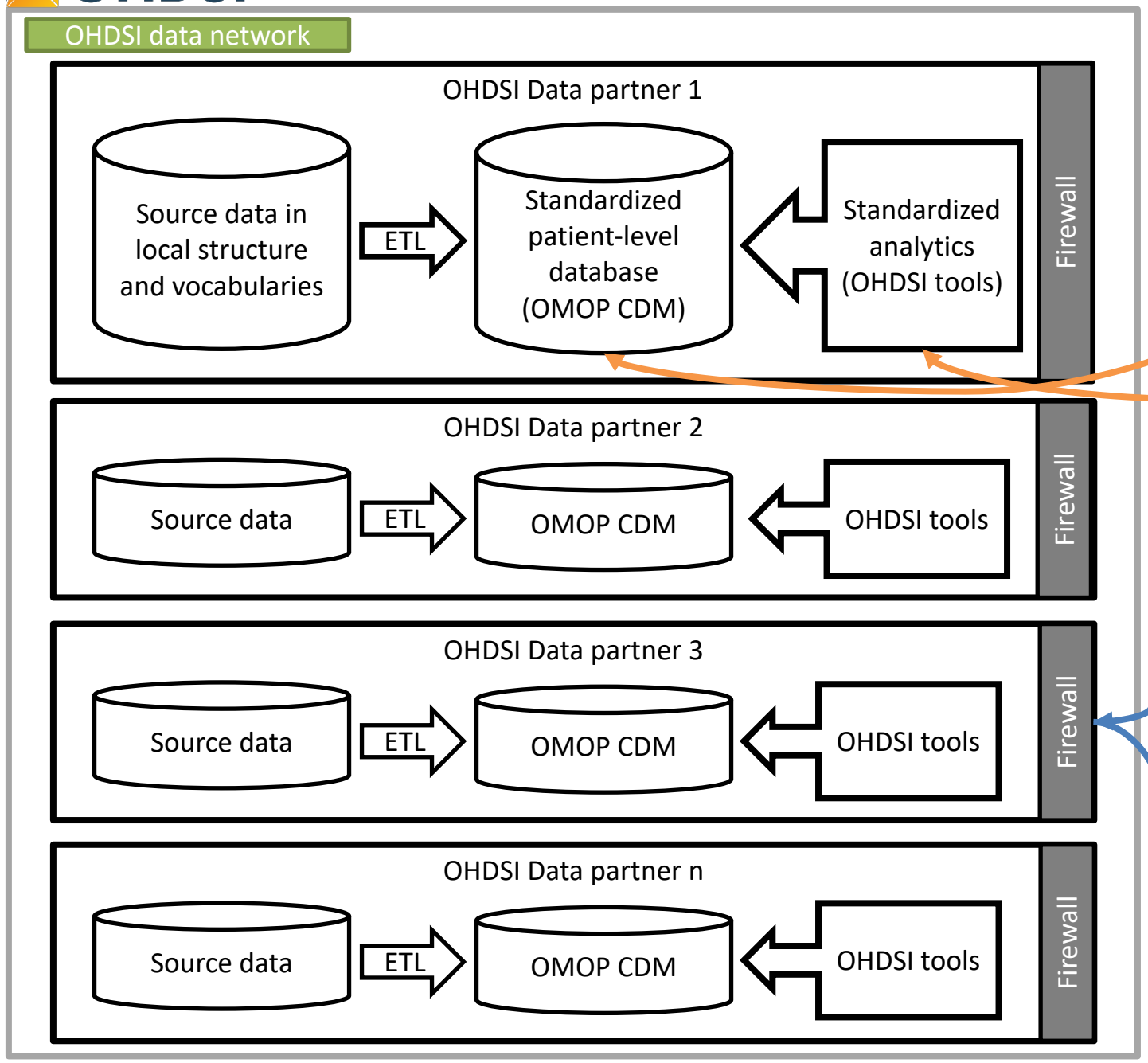
To improve health by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care

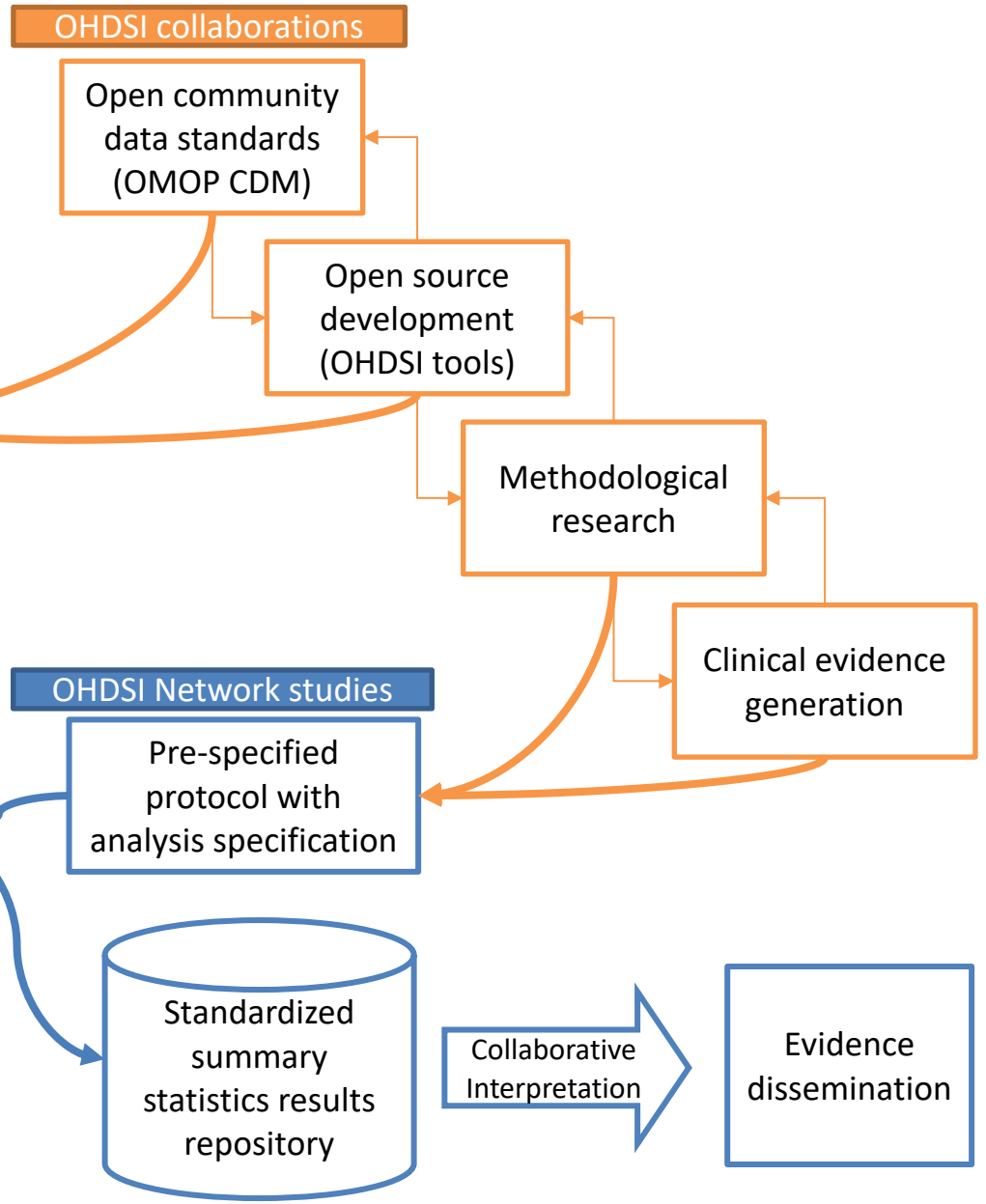
OHDSI's values

- **Innovation**: Observational research is a field which will benefit greatly from disruptive thinking. We actively seek and encourage fresh methodological approaches in our work.
- **Reproducibility**: Accurate, reproducible, and well-calibrated evidence is necessary for health improvement.
- **Community**: Everyone is welcome to actively participate in OHDSI, whether you are a patient, a health professional, a researcher, or someone who simply believes in our cause.
- **Collaboration**: We work collectively to prioritize and address the real world needs of our community's participants.
- **Openness**: We strive to make all our community's proceeds open and publicly accessible, including the methods, tools and the evidence that we generate.
- **Beneficence**: We seek to protect the rights of individuals and organizations within our community at all times.

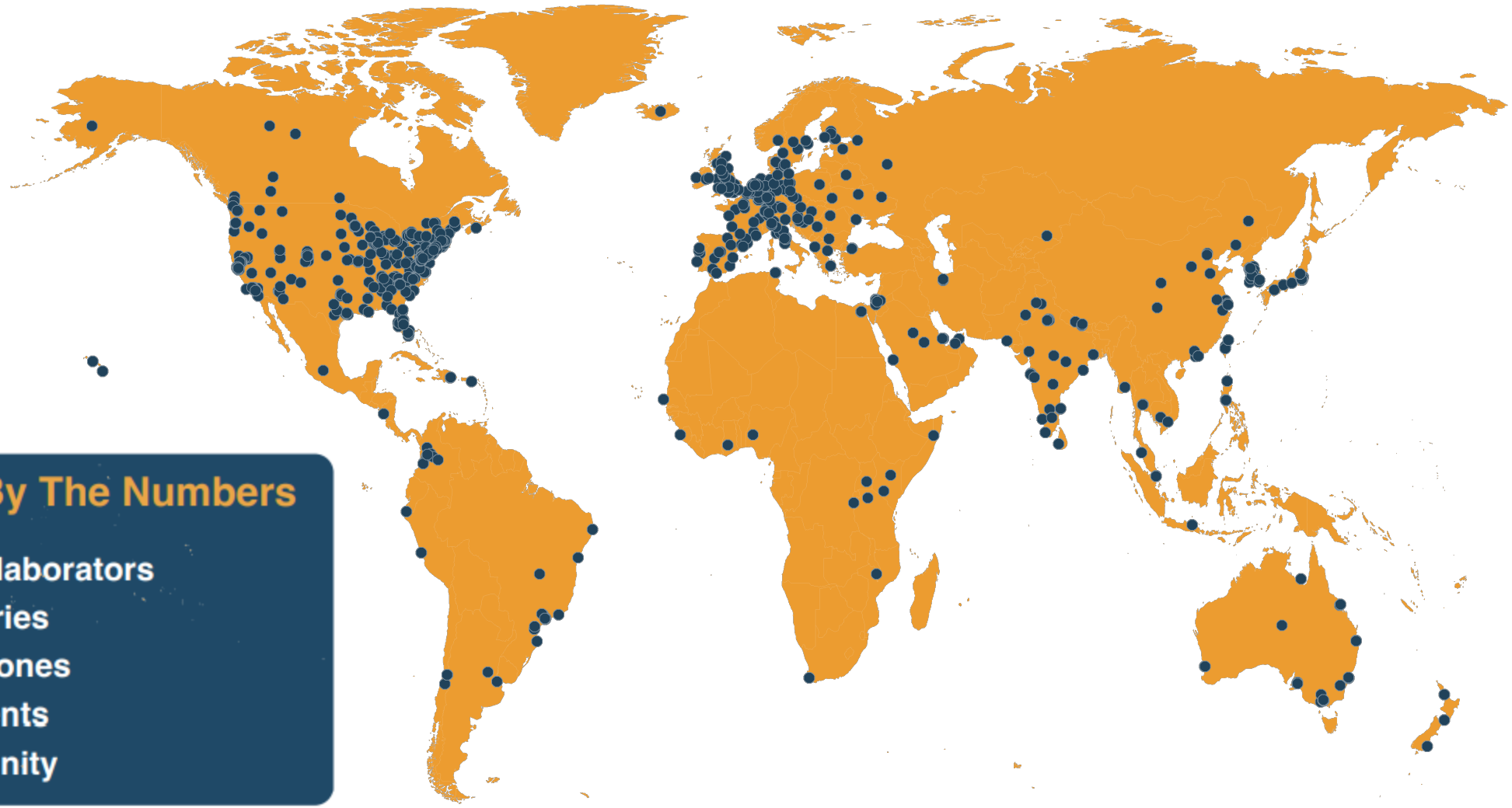
OHDSI

To improve health by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care





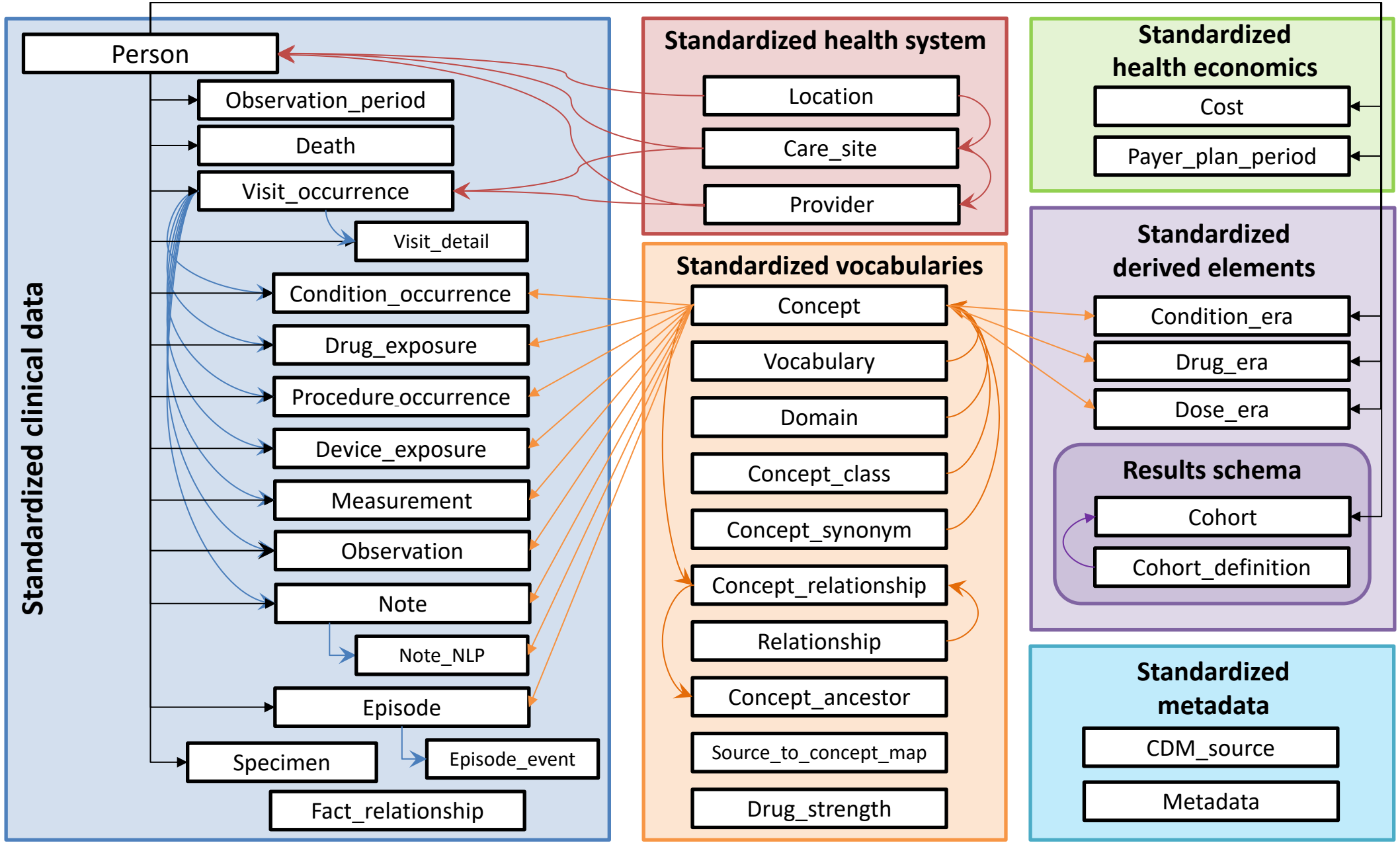
Map of collaborators



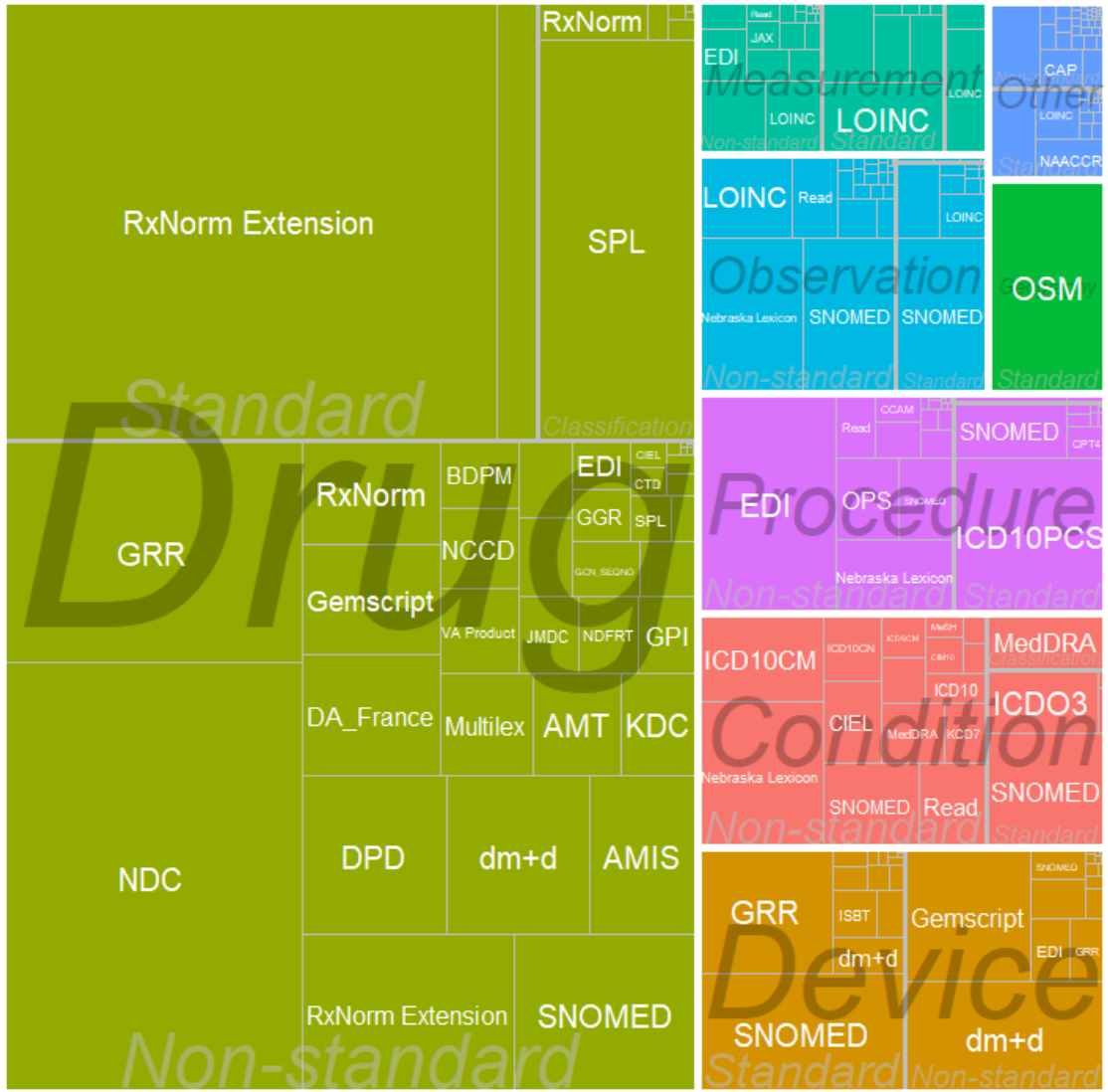
OHDSI By The Numbers

- 3,266 collaborators
- 80 countries
- 21 time zones
- 6 continents
- 1 community

OMOP Common Data Model



OHDSI vocabularies



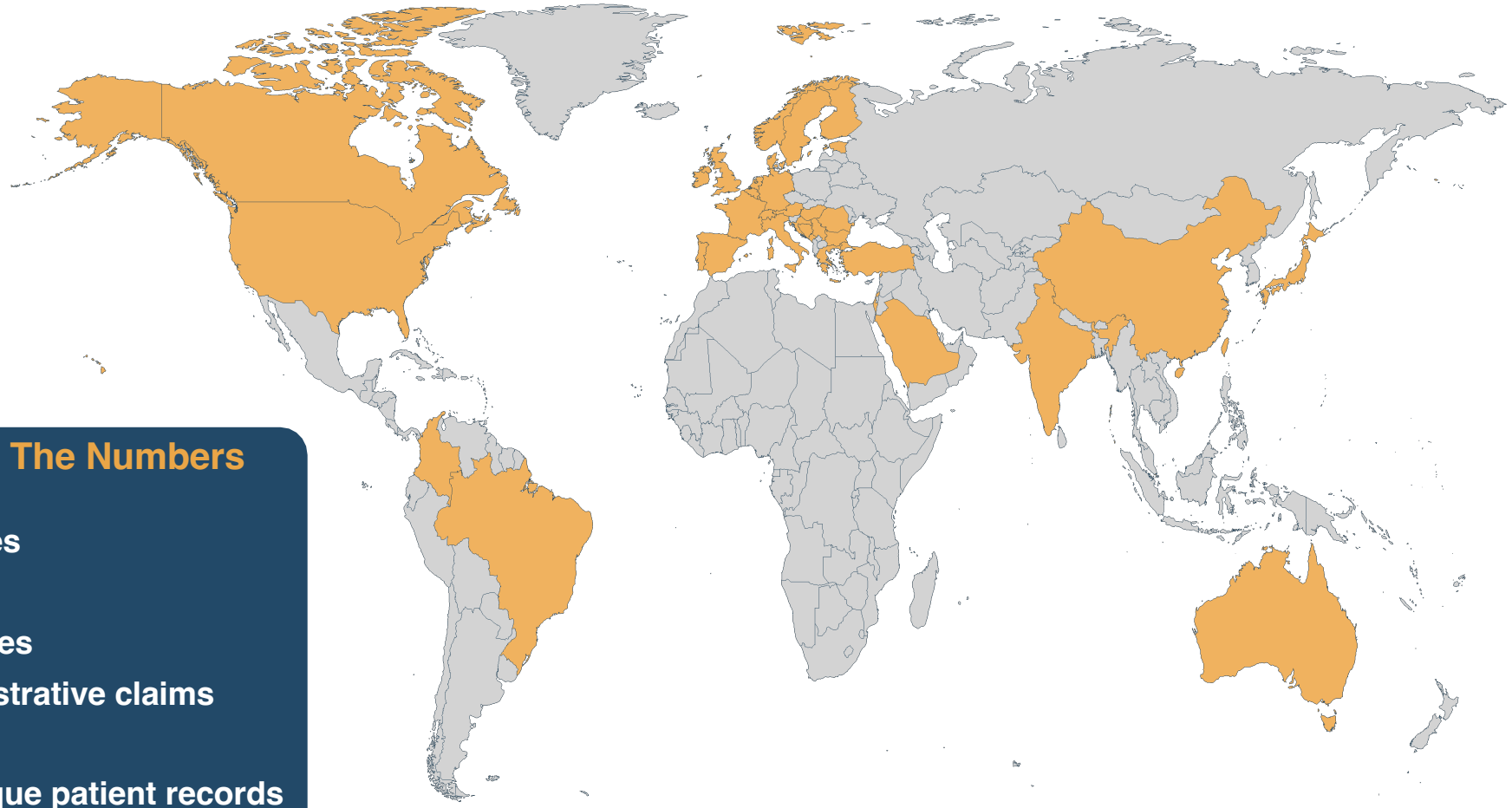
OHDSI Vocabularies By The Numbers

as of v5.0 · Sept. 9, 2022

- 10,218,572 concepts
  - 3,549,524 standard concepts
  - 780,207 classification concepts
- 135 vocabularies
- 42 domains
- 81,243,356 concept relationships
- 85,241,004 ancestral relationships
- 3,268,183 concept synonyms

1 Shared Resource to Enable Data Standards

OHDSI data partners



OHDSI Data By The Numbers

- 453 data sources
  - 374 EHRs
  - 34 registries
  - 30 administrative claims
- 41 countries
- 928 million unique patient records (12% of world's population)

OHDSI workgroups

APAC (Asia-Pacific)
Current Participants: 289
Lead: Mui Van Zandt

ATLAS/WebAPI
Current Participants: 226
Lead: Anthony Sena

Clinical Trials
Current Participants: 252
Leads: Mike Hamidi, Lin Zhen

Common Data Model
Current Participants: 596
Lead: Clair Blacketer

Data Quality Dashboard Development
Current Participants: 260
Lead: Clair Blacketer

Early-Stage Researchers
Current Participants: 214
Leads: Faaizah Arshad, Ross Williams

Medical Imaging
Current Participants: 114
Leads: Paul Nagy, Seng Chan You

Natural Language Processing
Current Participants: 379
Lead: Hua Xa

Oncology
Current Participants: 241
Lead: Asieh Golozar

Education
Current Participants: 116
Lead: Nigel Hughes

Eye Care & Vision Research
Current Participants: 40
Leads: Sally Baxter, Kerry Goetz

FHIR and OMOP
Current Participants: 214
Leads: Jon Duke, Christian Reich, Dana Stephenson

Open-Source Community
Current Participants: 118
Leads: Adam Black, Paul Nagy

Patient-Level Prediction
Current Participants: 355
Leads: Jenna Reps, Ross Williams

Phenotype Development & Evaluation
Current Participants: 249
Lead: Gowtham Rao

Geographic Information System (GIS)
Current Participants: 122
Leads: Robert Miller, Andrew Williams

HADES (Health Analytics Data-to-Evidence Suite)
Current Participants: 262
Lead: Martijn Schuemie

Health Equity
Current Participants: 201
Lead: Jake Gillberg

Population-Level Effect Estimation
Current Participants: 355
Leads: Martijn Schuemie, Marc Suchard

Psychiatry
Current Participants: 115
Leads: Dmitry Dymshyts, Andrew Williams

Registry
Current Participants: 115
Lead: Tina Parciak

Healthcare Systems
Current Participants: 430
Lead: Melanie Philofsky

Latin America
Current Participants: 48
Lead: Jose Posada

Medical Devices
Current Participants: 130
Leads: Vojtech Huser, Asiyah Lin

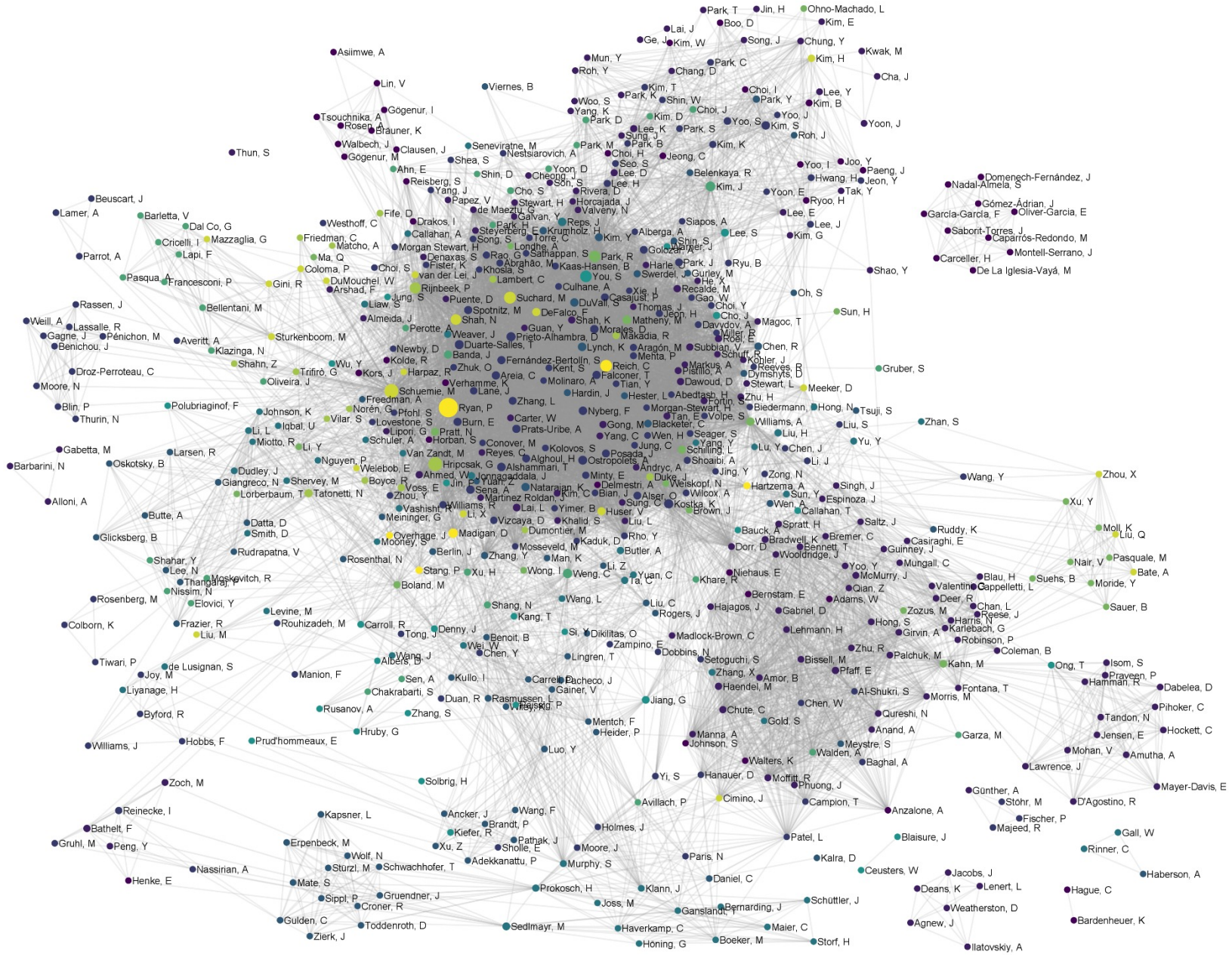
Steering Group
Current Participants: 70
Lead: Patrick Ryan

Surgery and Perioperative Medicine
Current Participants: 37
Lead: Evan Minty

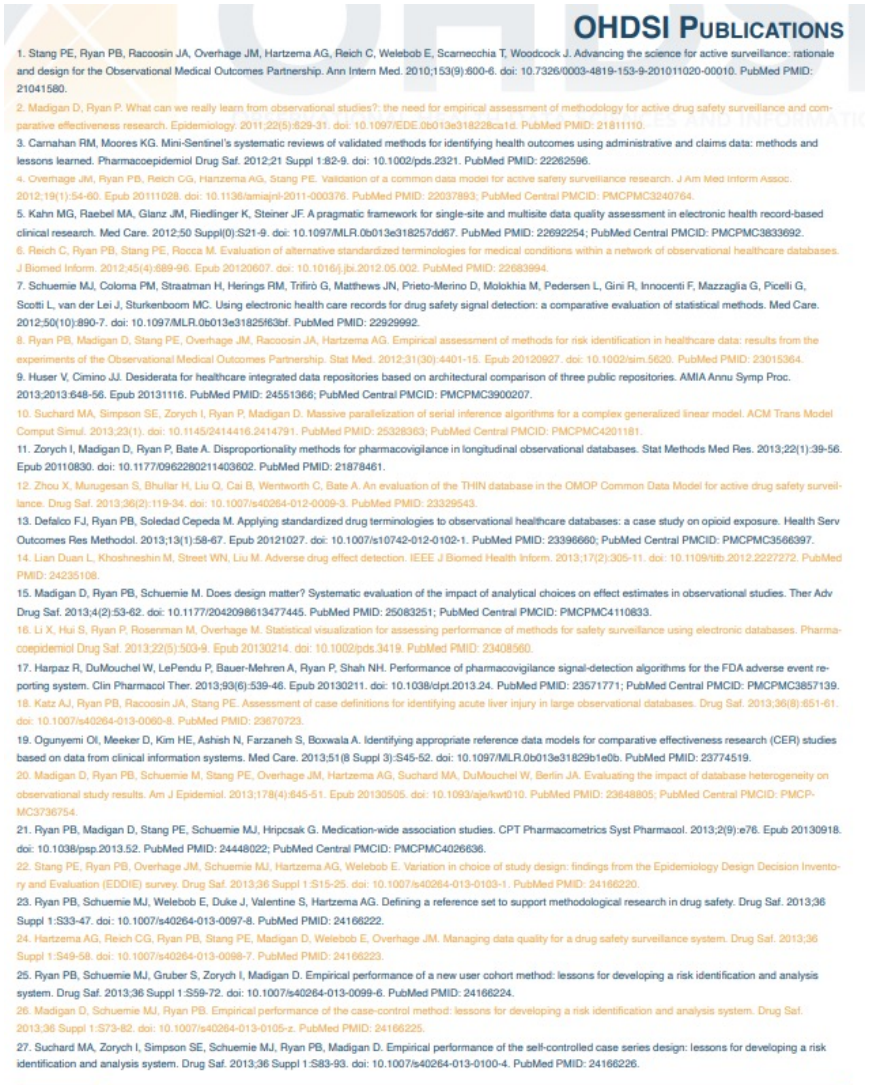
Vaccine Vocabulary
Current Participants: 76
Lead: Adam Black

OHDSI regional chapters

OHDSI publications



OHDSI publications

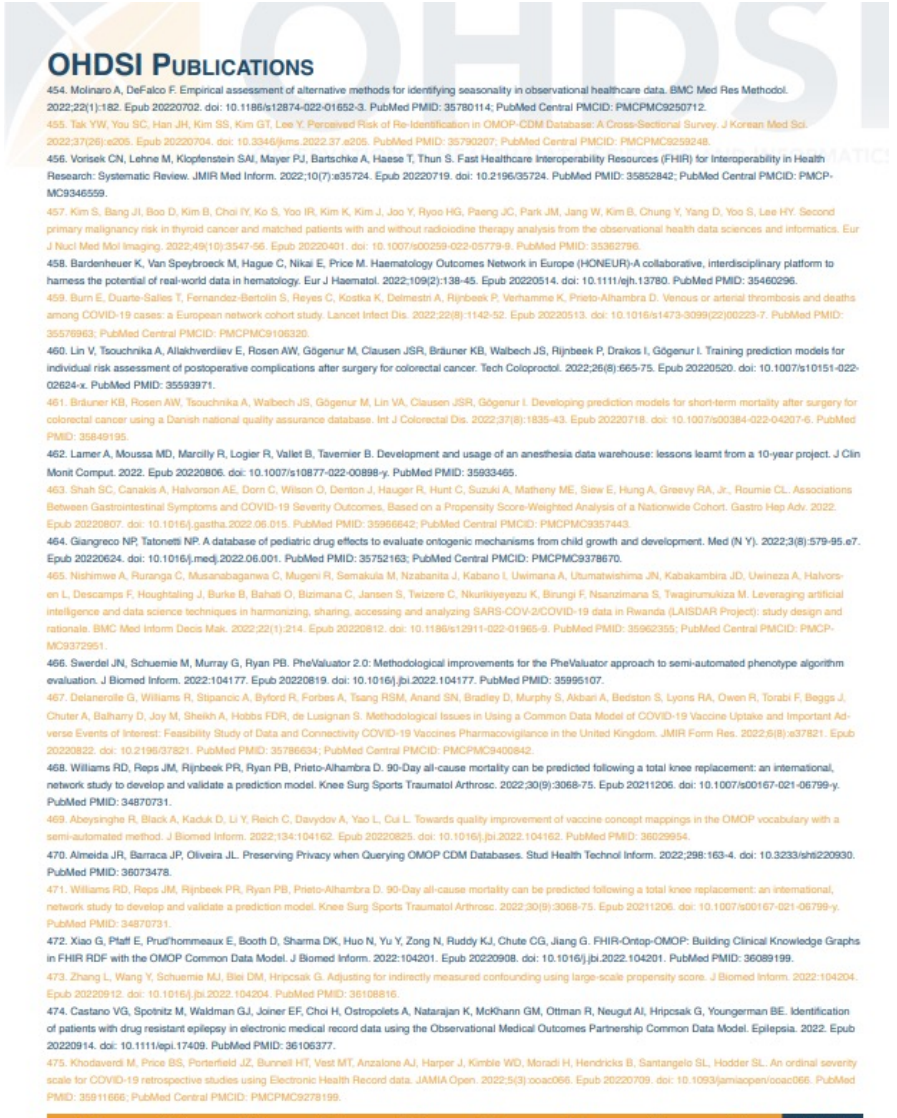


OHDSI Publications

1. Stang PE, Ryan PB, Racoosin JA, Overhage JM, Hartzema AG, Reich C, Welebob E, Scarnecchia T, Woodcock J. Advancing the science for active surveillance: rationale and design for the Observational Medical Outcomes Partnership. Ann Intern Med. 2010;153(9):600-6. doi: 10.7326/0003-4819-153-9-201011020-00010. PubMed PMID: 21041580.
2. Madigan D, Ryan P. What can we really learn from observational studies?: the need for empirical assessment of methodology for active drug safety surveillance and comparative effectiveness research. Epidemiology. 2011;22(5):629-31. doi: 10.1097/EDE.0b013e318228ca1d. PubMed PMID: 21811110.
3. Carnahan RM, Moores KG. Mini-Sentinel's systematic reviews of validated methods for identifying health outcomes using administrative and claims data: methods and lessons learned. Pharmacoepidemiol Drug Saf. 2012;21 Suppl 1:82-9. doi: 10.1002/pds.2321. PubMed PMID: 22262596.
4. Overhage JM, Ryan PB, Reich CG, Hartzema AG, Stang PE. Validation of a common data model for active safety surveillance research. J Am Med Inform Assoc. 2012;19(1):54-60. Epub 20111028. doi: 10.1136/amiajnl-2011-000376. PubMed PMID: 22037893; PubMed Central PMCID: PMCPMC3240764.
5. Kahn MG, Raebel MA, Glanz JM, Riedlinger K, Steiner JF. A pragmatic framework for single-site and multisite data quality assessment in electronic health record-based clinical research. Med Care. 2012;50 Suppl(0):S21-9. doi: 10.1097/MLR.0b013e318257dd67. PubMed PMID: 22692254; PubMed Central PMCID: PMCPMC3833692.
6. Reich C, Ryan PB, Stang PE, Rocca M. Evaluation of alternative standardized terminologies for medical conditions within a network of observational healthcare databases. J Biomed Inform. 2012;45(4):689-96. Epub 20120607. doi: 10.1016/j.jbi.2012.05.002. PubMed PMID: 22683994.
7. Schuemie MJ, Coloma PM, Straatman H, Herings RM, Trifirò G, Matthews JN, Prieto-Merino D, Molokhia M, Pedersen L, Gini R, Innocenti F, Mazzaglia G, Picelli G, Scotti L, van der Lei J, Sturkenboom MC. Using electronic health care records for drug safety signal detection: a comparative evaluation of statistical methods. Med Care. 2012;50(10):890-7. doi: 10.1097/MLR.0b013e31825f63bf. PubMed PMID: 22929992.
8. Ryan PB, Madigan D, Stang PE, Overhage JM, Racoosin JA, Hartzema AG. Empirical assessment of methods for risk identification in healthcare data: results from the experiments of the Observational Medical Outcomes Partnership. Stat Med. 2012;31(30):4401-15. Epub 20120927. doi: 10.1002/sim.5620. PubMed PMID: 23015364.
9. Huser V, Cimino JJ. Desiderata for healthcare integrated data repositories based on architectural comparison of three public repositories. AMIA Annu Symp Proc. 2013;2013:648-56. Epub 20131116. PubMed PMID: 24551366; PubMed Central PMCID: PMCPMC3900207.
10. Suchard MA, Simpson SE, Zorych I, Ryan P, Madigan D. Massive parallelization of serial inference algorithms for a complex generalized linear model. ACM Trans Model Comput Simul. 2013;23(1). doi: 10.1145/2414416.2414791. PubMed PMID: 25328363; PubMed Central PMCID: PMCPMC4201181.
11. Zorych I, Madigan D, Ryan P, Bate A. Disproportionality methods for pharmacovigilance in longitudinal observational databases. Stat Methods Med Res. 2013;22(1):39-56. Epub 20110830. doi: 10.1177/0962280211403602. PubMed PMID: 21878461.
12. Zhou X, Murugesan S, Bhullar H, Liu Q, Cai B, Wentworth C, Bate A. An evaluation of the THIN database in the OMOP Common Data Model for active drug safety surveillance. Drug Saf. 2013;36(2):119-34. doi: 10.1007/s40264-012-0009-3. PubMed PMID: 23329543.
13. Defalco FJ, Ryan PB, Soledad Cepeda M. Applying standardized drug terminologies to observational healthcare databases: a case study on opioid exposure. Health Serv Outcomes Res Methodol. 2013;13(1):58-67. Epub 20121027. doi: 10.1007/s10742-012-0102-1. PubMed PMID: 23396660; PubMed Central PMCID: PMCPMC3566397.
14. Lian Duan L, Khoshneshin M, Street WN, Liu M. Adverse drug effect detection. IEEE J Biomed Health Inform. 2013;17(2):305-11. doi: 10.1109/titb.2012.2227272. PubMed PMID: 24235108.
15. Madigan D, Ryan PB, Schuemie M. Does design matter? Systematic evaluation of the impact of analytical choices on effect estimates in observational studies. Ther Adv Drug Saf. 2013;4(2):53-62. doi: 10.1177/2042098613477445. PubMed PMID: 25083251; PubMed Central PMCID: PMCPMC4110833.
16. Li X, Hui S, Ryan P, Rosenman M, Overhage M. Statistical visualization for assessing performance of methods for safety surveillance using electronic databases. Pharmacoepidemiol Drug Saf. 2013;22(5):503-9. Epub 20130214. doi: 10.1002/pds.3419. PubMed PMID: 23408560.
17. Harpaz R, DuMouchel W, LePendu P, Bauer-Mehren A, Ryan P, Shah NH. Performance of pharmacovigilance signal-detection algorithms for the FDA adverse event reporting system. Clin Pharmacol Ther. 2013;93(6):539-46. Epub 20130211. doi: 10.1038/clpt.2013.24. PubMed PMID: 23571771; PubMed Central PMCID: PMCPMC3857139.
18. Katz AJ, Ryan PB, Racoosin JA, Stang PE. Assessment of case definitions for identifying acute liver injury in large observational databases. Drug Saf. 2013;36(8):651-61. doi: 10.1007/s40264-013-0060-8. PubMed PMID: 23870723.
19. Ogunyemi OI, Meeker D, Kim HE, Ashish N, Farzaneh S, Boxwala A. Identifying appropriate reference data models for comparative effectiveness research (CER) studies based on data from clinical information systems. Med Care. 2013;51(8 Suppl 3):S45-52. doi: 10.1097/MLR.0b013e31829b1e0b. PubMed PMID: 23774519.
20. Madigan D, Ryan PB, Schuemie M, Stang PE, Overhage JM, Hartzema AG, Suchard MA, DuMouchel W, Berlin JA. Evaluating the impact of database heterogeneity on observational study results. Am J Epidemiol. 2013;178(4):645-51. Epub 20130505. doi: 10.1093/aje/kwt010. PubMed PMID: 23648805; PubMed Central PMCID: PMCPMC3736754.
21. Ryan PB, Madigan D, Stang PE, Schuemie MJ, Hripcsak G. Medication-wide association studies. CPT Pharmacometrics Syst Pharmacol. 2013;2(9):e76. Epub 20130918. doi: 10.1038/psp.2013.52. PubMed PMID: 24448022; PubMed Central PMCID: PMCPMC4026636.
22. Stang PE, Ryan PB, Overhage JM, Schuemie MJ, Hartzema AG, Welebob E. Variation in choice of study design: findings from the Epidemiology Design Decision Inventory and Evaluation (EDDIE) survey. Drug Saf. 2013;36 Suppl 1:S15-25. doi: 10.1007/s40264-013-0103-1. PubMed PMID: 24166220.
23. Ryan PB, Schuemie MJ, Welebob E, Duke J, Valentine S, Hartzema AG. Defining a reference set to support methodological research in drug safety. Drug Saf. 2013;36 Suppl 1:S33-47. doi: 10.1007/s40264-013-0097-8. PubMed PMID: 24166222.
24. Hartzema AG, Reich CG, Ryan PB, Stang PE, Madigan D, Welebob E, Overhage JM. Managing data quality for a drug safety surveillance system. Drug Saf. 2013;36 Suppl 1:S49-58. doi: 10.1007/s40264-013-0098-7. PubMed PMID: 24166223.
25. Ryan PB, Schuemie MJ, Gruber S, Zorych I, Madigan D. Empirical performance of a new user cohort method: lessons for developing a risk identification and analysis system. Drug Saf. 2013;36 Suppl 1:S59-72. doi: 10.1007/s40264-013-0099-6. PubMed PMID: 24166224.
26. Madigan D, Schuemie MJ, Ryan PB. Empirical performance of the case-control method: lessons for developing a risk identification and analysis system. Drug Saf. 2013;36 Suppl 1:S73-82. doi: 10.1007/s40264-013-0105-z. PubMed PMID: 24166225.
27. Suchard MA, Zorych I, Simpson SE, Schuemie MJ, Ryan PB, Madigan D. Empirical performance of the self-controlled case series design: lessons for developing a risk identification and analysis system. Drug Saf. 2013;36 Suppl 1:S83-93. doi: 10.1007/s40264-013-0100-4. PubMed PMID: 24166226.

≤ 2013	2014	2015	2016	2017	2018	2019	2020	2021	Thru Sept '22
33	14	21	20	29	36	53	83	103	83

22 pages highlighting the **475** publications from our community



OHDSI Publications

454. Molinaro A, DeFalco F. Empirical assessment of alternative methods for identifying seasonality in observational healthcare data. BMC Med Res Methodol. 2022;22(1):182. Epub 20220702. doi: 10.1186/s12874-022-01652-3. PubMed PMID: 35780114; PubMed Central PMCID: PMCPMC9250712.
455. Tak YW, You SC, Han JH, Kim SS, Kim GT, Lee Y. Perceived Risk of Re-Identification in OMOP-CDM Database: A Cross-Sectional Survey. J Korean Med Sci. 2022;37(26):e205. Epub 20220704. doi: 10.3346/jkms.2022.37.e205. PubMed PMID: 35790207; PubMed Central PMCID: PMCPMC9259248.
456. Vorisek CN, Lehne M, Klopfenstein SAI, Mayer PJ, Bartschke A, Haese T, Thun S. Fast Healthcare Interoperability Resources (FHIR) for Interoperability in Health Research: Systematic Review. JMIR Med Inform. 2022;10(7):e35724. Epub 20220719. doi: 10.2196/35724. PubMed PMID: 35852842; PubMed Central PMCID: PMCPMC9346559.
457. Kim S, Bang JI, Boo D, Kim B, Choi IY, Ko S, Yoo IR, Kim K, Kim J, Joo Y, Ryoo HG, Paeng JC, Park JM, Jang W, Kim B, Chung Y, Yang D, Yoo S, Lee HY. Second primary malignancy risk in thyroid cancer and matched patients with and without radioiodine therapy analysis from the observational health data sciences and informatics. Eur J Nucl Med Mol Imaging. 2022;49(10):3547-56. Epub 20220401. doi: 10.1007/s00259-022-05779-9. PubMed PMID: 35362796.
458. Bardenheuer K, Van Speybroeck M, Hague C, Nikai E, Price M. Haematology Outcomes Network in Europe (HONEUR)-A collaborative, interdisciplinary platform to harness the potential of real-world data in hematology. Eur J Haematol. 2022;109(2):138-45. Epub 20220514. doi: 10.1111/ejh.13780. PubMed PMID: 35460296.
459. Burn E, Duarte-Salles T, Fernandez-Bertolin S, Reyes C, Kostka K, Delmestri A, Rijnbeek P, Verhamme K, Prieto-Alhambra D. Venous or arterial thrombosis and deaths among COVID-19 cases: a European network cohort study. Lancet Infect Dis. 2022;22(8):1142-52. Epub 20220513. doi: 10.1016/s1473-3099(22)00223-7. PubMed PMID: 35576963; PubMed Central PMCID: PMCPMC9106320.
460. Lin V, Tsouchnika A, Allakhverdiev E, Rosen AW, Gögenur M, Clausen JSR, Bräuner KB, Walbech JS, Rijnbeek P, Drakos I, Gögenur I. Training prediction models for individual risk assessment of postoperative complications after surgery for colorectal cancer. Tech Coloproctol. 2022;26(8):665-75. Epub 20220520. doi: 10.1007/s10151-022-02624-x. PubMed PMID: 35593971.
461. Bräuner KB, Rosen AW, Tsouchnika A, Walbech JS, Gögenur M, Lin VA, Clausen JSR, Gögenur I. Developing prediction models for short-term mortality after surgery for colorectal cancer using a Danish national quality assurance database. Int J Colorectal Dis. 2022;37(8):1835-43. Epub 20220718. doi: 10.1007/s00384-022-04207-6. PubMed PMID: 35849195.
462. Lamer A, Moussa MD, Marcilly R, Logier R, Vallet B, Tavernier B. Development and usage of an anesthesia data warehouse: lessons learnt from a 10-year project. J Clin Monit Comput. 2022. Epub 20220806. doi: 10.1007/s10877-022-00898-y. PubMed PMID: 35933465.
463. Shah SC, Canakis A, Halvorson AE, Dorn C, Wilson O, Denton J, Hauger R, Hunt C, Suzuki A, Matheny ME, Siew E, Hung A, Greevy RA, Jr., Roumie CL. Associations Between Gastrointestinal Symptoms and COVID-19 Severity Outcomes, Based on a Propensity Score-Weighted Analysis of a Nationwide Cohort. Gastro Hep Adv. 2022. Epub 20220807. doi: 10.1016/j.gastha.2022.06.015. PubMed PMID: 35966642; PubMed Central PMCID: PMCPMC9357443.
464. Giangreco NP, Tatonetti NP. A database of pediatric drug effects to evaluate ontogenic mechanisms from child growth and development. Med (N Y). 2022;3(8):579-95.e7. Epub 20220624. doi: 10.1016/j.medj.2022.06.001. PubMed PMID: 35752163; PubMed Central PMCID: PMCPMC9378670.
465. Nishimwe A, Ruranga C, Musanabaganwa C, Mugeni R, Semakula M, Nzabanita J, Kabano I, Uwimana A, Utumatwishima JN, Kabakambira JD, Uwineza A, Halvorsen L, Descamps F, Houghtaling J, Burke B, Bahati O, Bizimana C, Jansen S, Twizere C, Nkurikiyeyezu K, Birungi F, Nsanzimana S, Twagirumukiza M. Leveraging artificial intelligence and data science techniques in harmonizing, sharing, accessing and analyzing SARS-COV-2/COVID-19 data in Rwanda (LAISDAR Project): study design and rationale. BMC Med Inform Decis Mak. 2022;22(1):214. Epub 20220812. doi: 10.1186/s12911-022-01965-9. PubMed PMID: 35962355; PubMed Central PMCID: PMCPMC9372951.
466. Swerdel JN, Schuemie M, Murray G, Ryan PB. PheValuator 2.0: Methodological improvements for the PheValuator approach to semi-automated phenotype algorithm evaluation. J Biomed Inform. 2022:104177. Epub 20220819. doi: 10.1016/j.jbi.2022.104177. PubMed PMID: 35995107.
467. Delanerolle G, Williams R, Stipancic A, Byford R, Forbes A, Tsang RSM, Anand SN, Bradley D, Murphy S, Akbari A, Bedston S, Lyons RA, Owen R, Torabi F, Beggs J, Chuter A, Balharry D, Joy M, Sheikh A, Hobbs FDR, de Lusignan S. Methodological Issues in Using a Common Data Model of COVID-19 Vaccine Uptake and Important Adverse Events of Interest: Feasibility Study of Data and Connectivity COVID-19 Vaccines Pharmacovigilance in the United Kingdom. JMIR Form Res. 2022;6(8):e37821. Epub 20220822. doi: 10.2196/37821. PubMed PMID: 35786634; PubMed Central PMCID: PMCPMC9400842.
468. Williams RD, Reps JM, Rijnbeek PR, Ryan PB, Prieto-Alhambra D. 90-Day all-cause mortality can be predicted following a total knee replacement: an international, network study to develop and validate a prediction model. Knee Surg Sports Traumatol Arthrosc. 2022;30(9):3068-75. Epub 20211206. doi: 10.1007/s00167-021-06799-y. PubMed PMID: 34870731.
469. Abeysinghe R, Black A, Kaduk D, Li Y, Reich C, Davydov A, Yao L, Cui L. Towards quality improvement of vaccine concept mappings in the OMOP vocabulary with a semi-automated method. J Biomed Inform. 2022;134:104162. Epub 20220825. doi: 10.1016/j.jbi.2022.104162. PubMed PMID: 36029954.
470. Almeida JR, Barraca JP, Oliveira JL. Preserving Privacy when Querying OMOP CDM Databases. Stud Health Technol Inform. 2022;298:163-4. doi: 10.3233/shti220930. PubMed PMID: 36073478.
471. Williams RD, Reps JM, Rijnbeek PR, Ryan PB, Prieto-Alhambra D. 90-Day all-cause mortality can be predicted following a total knee replacement: an international, network study to develop and validate a prediction model. Knee Surg Sports Traumatol Arthrosc. 2022;30(9):3068-75. Epub 20211206. doi: 10.1007/s00167-021-06799-y. PubMed PMID: 34870731.
472. Xiao G, Pfaff E, Prud'hommeaux E, Booth D, Sharma DK, Huo N, Yu Y, Zong N, Ruddy KJ, Chute CG, Jiang G. FHIR-Ontop-OMOP: Building Clinical Knowledge Graphs in FHIR RDF with the OMOP Common Data Model. J Biomed Inform. 2022:104201. Epub 20220908. doi: 10.1016/j.jbi.2022.104201. PubMed PMID: 36089199.
473. Zhang L, Wang Y, Schuemie MJ, Blei DM, Hripcsak G. Adjusting for indirectly measured confounding using large-scale propensity score. J Biomed Inform. 2022:104204. Epub 20220912. doi: 10.1016/j.jbi.2022.104204. PubMed PMID: 36108816.
474. Castano VG, Spotnitz M, Waldman GJ, Joiner EF, Choi H, Ostropolets A, Natarajan K, McKhann GM, Ottman R, Neugut AI, Hripcsak G, Youngerman BE. Identification of patients with drug resistant epilepsy in electronic medical record data using the Observational Medical Outcomes Partnership Common Data Model. Epilepsia. 2022. Epub 20220914. doi: 10.1111/epi.17409. PubMed PMID: 36106377.
475. Khodaverdi M, Price BS, Porterfield JZ, Bunnell HT, Vest MT, Anzalone AJ, Harper J, Kimble WD, Moradi H, Hendricks B, Santangelo SL, Hodder SL. An ordinal severity scale for COVID-19 retrospective studies using Electronic Health Record data. JAMIA Open. 2022;5(3):ooac066. Epub 20220709. doi: 10.1093/jamiaopen/ooac066. PubMed PMID: 35911666; PubMed Central PMCID: PMCPMC9278199.

>2013	2014	2015	2016	2017	2018	2019	2020	2021	Thru Sept '22
33	14	21	20	29	36	53	83	103	80

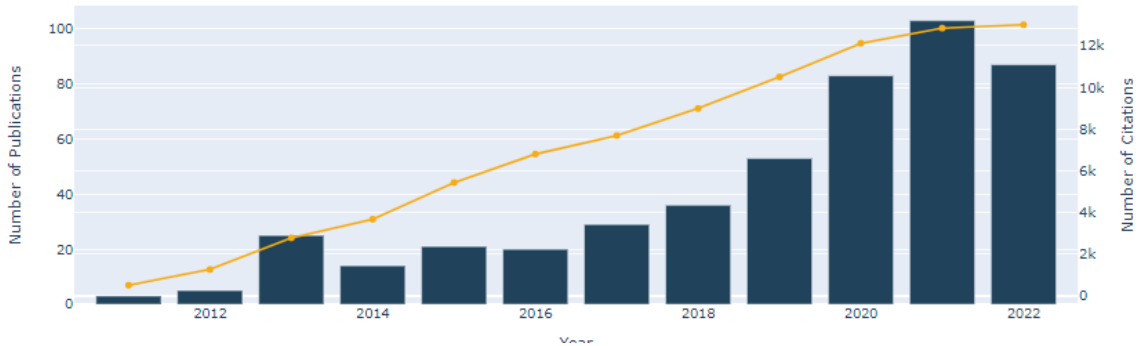
OHDSI community dashboard: Publications

OHDSI Community Dashboard Dashboards

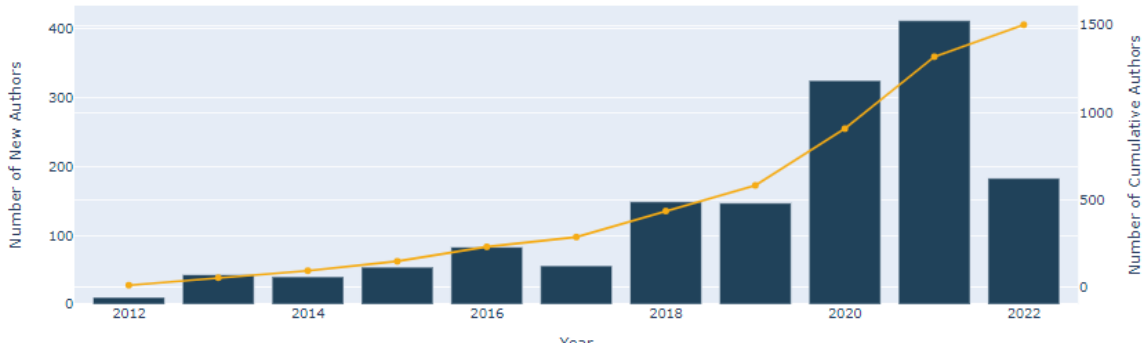
Publication Analysis

PubMed Publication Tracking highlights scholarship generated using the OMOP Common Data Model, OHDSI tools, or the OHDSI network. These publications represent scientific accomplishments across areas of data standards, methodological research, open-source development, and clinical applications. We provide the resource to search and browse the catalogue of OHDSI-related publications by date, author, title, journal, and SNOMED terms. We monitor the impact of our community using summary statistics (number of publications and citations), and the growth and diversity of our community with the number of distinct authors. Searches for new papers are performed daily, and citation counts are updated monthy.

OHDSI Publications & Cumulative Citations



New and Cumulative OHDSI Researchers



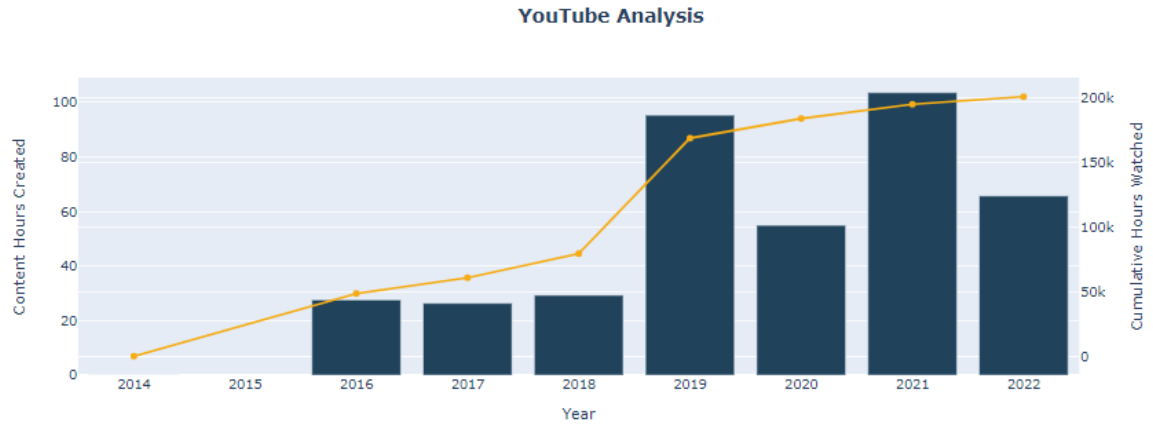
Explore our community progress:
http://dash.ohdsi.org

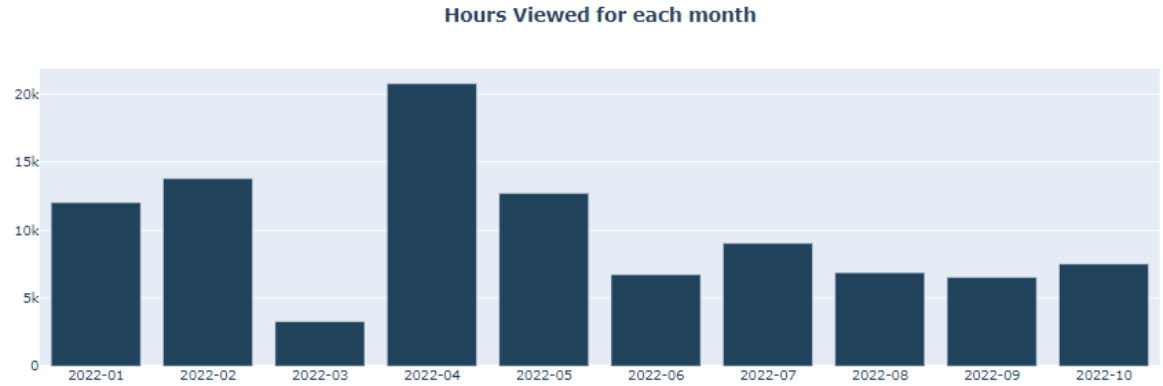
OHDSI community dashboard: Educational content

OHDSI Community Dashboard Dashboards

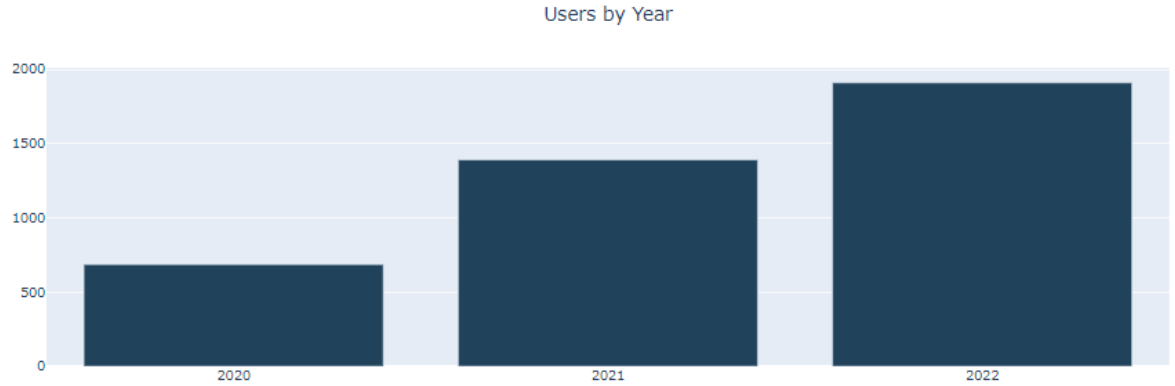
YouTube Analysis

Youtube Tracking leverages the Google YouTube Data API and highlights videos released across the OHDSI Youtube Channels. These videos are intended to serve two purposes: 1) provide users a great source of training on learning how to conduct observational research. 2) keep our community aware of the latest activities within our open science community. Searches for new videos are performed daily.

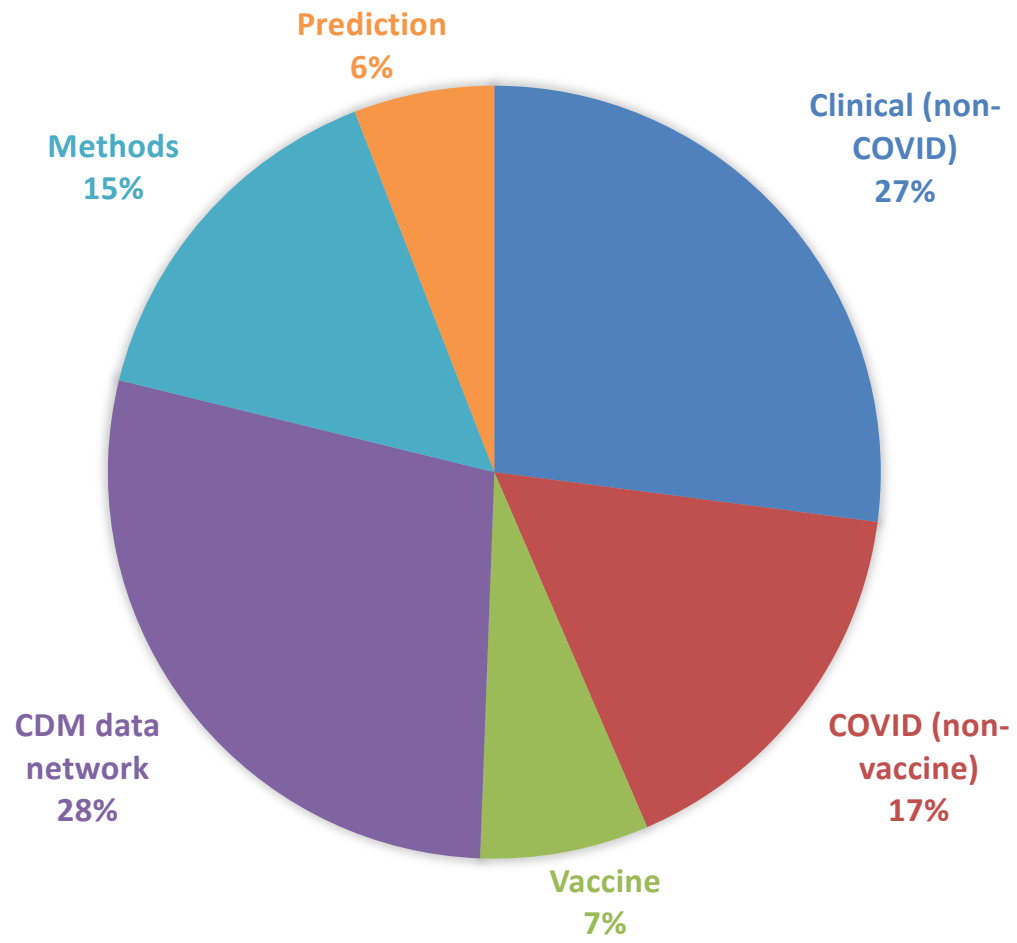




Ehden Learning Management System Analysis



80 publications Jan-Sep 2022



- Strict hierarchy so some interpretation
- Getting close to half clinical
- Strong COVID from 2020-2021
  - Vaccine
- CDM includes standard and data network, often by outside researchers
- Methods includes tools, with analysis and phenotyping
- Prediction small but increasing

Phenotype Phebrurary Feb 2022

Phenotype Phebruary • Daily Threads & What We Learned

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

This page will provide direct links to each forum post, which is where conversations around each specific phenotype should be held. The video on the right includes "phun phacts" shared about each phenotype during our weekly community calls.

Daily Phenotype Phebruary Links

(future dates are subject to change)

Feb. 1 • Type 2 Diabetes Mellitus
Feb. 2 • Type 1 Diabetes Mellitus
Feb. 3 • Atrial Fibrillation
Feb. 4 • Multiple Myeloma
Feb. 5 • Alzheimer's Disease
Feb. 6 • Hemorrhagic Events
Feb. 7 • Neutropenia
Feb. 8 • Kidney Stones
Feb. 9 • Delirium
Feb. 10 • Systemic Lupus Erythematosus
Feb. 11 • Suicide Attempts
Feb. 12 • Parkinson's Disease and Parkinsonism
Feb. 13 • Attention Deficit Hyperactivity Disorder
Feb. 14 • Hypertension *(Video Description)*
Feb. 15 • Acute Myocardial Infarction
Feb. 16 • Heart Failure
Feb. 17 • Cardiomyopathy
Feb. 18 • Multiple Sclerosis
Feb. 19 • Triple Negative Breast Cancer
Feb. 20 • Pulmonary Hypertension
Feb. 21 • Prostate Cancer
Feb. 22 • HIV
Feb. 23 • Hidradenitis Suppurativa
Feb. 24 • Anaphylaxis
Feb. 25 • Depression
Feb. 26 • Non-Small-Cell Lung Cancer
Feb. 27 • Drug-Induced Liver Injury
Feb. 28 • Severe Visual Impairment And Blindness
Bonus • Acute Kidney Injury

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

OHDSI DevCon April 2022

OHDSI DevCon 2022 Welcomes & Mentors New Contributors To Our Open-Source Environment

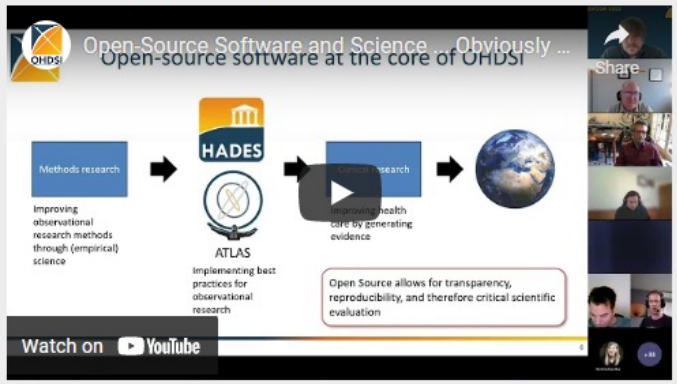
Watch All Eight Workshops, Talks & The Panel From DevCon Below

The Open-Source Community hosted the first Dev Con on Friday, April 22 as a way of accepting and mentoring new contributors to our environment. Organized by **Paul Nagy** and **Adam Black**, the event included eight workshops, talks and a panel discussion to both welcome and engage both current and future developers within OHDSI.

All videos from this session have or will be uploaded to this page. A big announcement from DevCon was the formation of the Khieron Contributor Cohort, which will help onboard and mentor open-source developers in the community. If you are interested in joining the effort, please fill out the application.

To learn more about the Khieron Contributor Cohort, please check out the State of the Open Source Community presentation below.

OHDSI DevCon Keynote



Martijn Schuemie provided the keynote address during DevCon 2022, entitled "Open-Source Software and Science … Obviously." His slides are available here.

State Of The Community Presentation

Panel: Putting The Pieces Together

Workshops

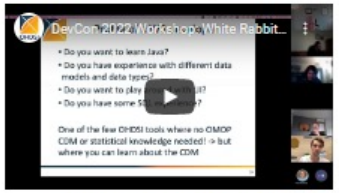
ATLAS (Anthony Sena)

HADES Introduction (Adam Black)

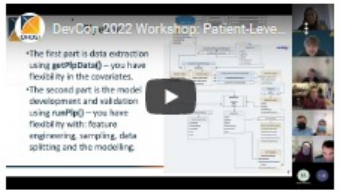
WebAPI (Anthony Sena)

Cohort Diagnostics (James Gilbert)

White Rabbit (Maxim Moinat)



Patient-Level Prediction (Jenna Reps)



Data Quality Dashboard (Clair Blacketer)

Cyclops (Marc Suchard)

https://www.ohdsi.org/devcon2022/

Establishing agreements to enable community to apply open data standards and content

"Through the collaboration, SNOMED CT will be available to all OHDSI users for use in its products. Additionally, SNOMED International will work with OHDSI to provide SNOMED CT Development Licenses to users in non-member countries."

https://www.snomed.org/news-and-events/articles/SNOMED-OHDSI-2022-collaboration

OHDSI partners collaborating to support EMA through DARWIN-EU

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Search

Medicines | Human regulatory | Veterinary regulatory | Committees | News & events | Partners & networks | About us

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

Share

News 09/02/2022

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

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

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

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

For example, the availability of timely and reliable real-world evidence can lead to innovative medicines becoming more quickly available to patients. Better evidence also supports more informed regulatory decision-making on the safe and effective use by patients of medicines on the market.

EMA will be working with Erasmus University Medical Center Rotterdam to establish the DARWIN EU® Coordination Centre. The contract was awarded to Erasmus University Medical Center Rotterdam following a call for tender for a service provider published in June 2021. The contractor will set up the necessary

https://www.ema.europa.eu/en/news/initiation-darwin-eur-coordination-centre-advances-integration-real-world-evidence-assessment

Estimation

Evaluating performance of vaccine evaluation methods

FDA U.S. FOOD & DRUG ADMINISTRATION

Center for Biologics Evaluation and Research
Office of Biostatistics and Epidemiology

CBER Surveillance Program

COVID-19 Vaccine Safety Surveillance: Active Monitoring Master Protocol

February 10, 2021

OHDSI

RESEARCH PROTOCOL

EUMAEUS: Evaluating Use of Methods for Adverse Event Under Surveillance (for vaccines)

Version: 1.2.0

1 List of Abbreviations

AUC	Area Under the receiver-operator Curve
CCAE	IBM MarketScan Commercial Claims and Encounters
CDM	Common Data Model
CIOMS	Council for International Organizations of Medical Sciences
COVID-19	COronaVirus Disease 2019
CPRD	Clinical Practice Research Datalink
CRAN	Comprehensive R Archive Network
EHR	Electronic Health Record
EMA	European Medicines Agency

frontiers | Frontiers in Pharmacology

ORIGINAL RESEARCH
published: 26 April 2022
doi: 10.3389/fphar.2022.814198

Factors Influencing Background Incidence Rate Calculation: Systematic Empirical Evaluation Across an International Network of Observational Databases

OPEN ACCESS

Anna Ostropolets[17], Xintong Li[2†], Rupa Maka
Talita Duarte-Salles[5], Anthony G. Sena[3,4], Azz
Patrick B. Ryan[1,3], Daniel Prieto-Alhambra[2] a

[1]Columbia University Medical Center, New York, NY, United St
Oxford, Oxford, United Kingdom, [3]Janssen Research and Deve
Informatics, Erasmus University Medical Center, Rotterdam, Ne

Edited by:
Elisabetta Poluzzi,
University of Bologna, Italy

Evaluating Use of Methods for Adverse Event Under Surveillance (EUMAEUS)

About | Effect-size-estimate-based metrics | MaxSPRT-based metrics | Database information

Vaccine: H1N1 vaccination
Empirical calibration: Uncalibrated
Database: CCAE
Time at risk: 1-28
True effect size: Overall

Per period | Across periods | Across periods & methods

Time period: 9 months

Show 10 entries

Method	ID	AUC	Coverage	Mean Precision	MSE	Type I error	Type II error	Non-estimable
CohortMethod	26	0.94	0.87	12.43	0.19	0.04	0.15	0.14
HistoricalComparator	16	0.94	0.6	33.94	0.12	0.18	0.1	0.11
SCCS	3	0.94	0.78	14.86	0.16	0.08	0.07	0.11
CohortMethod	4	0.93	0.86	13.1	0.24	0.05	0.12	0.12
CohortMethod	14	0.93	0.84	19.29	0.18	0.08	0.06	0.11
HistoricalComparator	2	0.93	0.47	37.06	0.2	0.3	0.02	0.1
HistoricalComparator	4	0.93	0.6	34.24	0.12	0.18	0.1	0.1
HistoricalComparator	13	0.93	0.6	36.83	0.17	0.18	0.04	0.11

frontiers | Frontiers in Pharmacology

ORIGINAL RESEARCH
published: 06 July 2022

Vaccine Safety Surveillance Using Routinely Collected Healthcare Data —An Empirical Evaluation of Epidemiological Designs

Martijn J. Schuemie[1,2,3*], Faaizah Arshad[1,2], Nicole Pratt[4], Fredrik Nyberg[5], Thamir M Alshammari[6], George Hripcsak[1,7], Patrick Ryan[1,2,7], Daniel Prieto-Alhambra[8,9], Lana Y. H. Lai[10], Xintong Li[11], Stephen Fortin[2], Evan Minty[10] and Marc A. Suchard[1,3,12]

[1]Observational Health Data Sciences and Informatics, New York, NY, United States, [2]Observational Health Data Analytics, Janssen R&D, Titusville, NJ, United States, [3]Department of Biostatistics, University of California, Los Angeles, Los Angeles, CA, United States, [4]Quality Use of Medicines and Pharmacy Research Centre, Clinical and Health Sciences, University of South

Drug Safety (2022) 45:685–698
https://doi.org/10.1007/s40264-022-01187-y

ORIGINAL RESEARCH ARTICLE

Phenotype Algorithms for the Identification and Characterization of Vaccine-Induced Thrombotic Thrombocytopenia in Real World Data: A Multinational Network Cohort Study

Azza Shoaibi[1,2] · Gowtham A. Rao[1,2] · Erica A. Voss[1,2] · Anna Ostropolets[2,3] · Miguel Angel Mayer[4] · Juan Manuel Ramirez-Anguita[4] · Filip Maljković[5] · Biljana Carević[6] · Scott Horban[7] · Daniel R. Morales[7] · Talita Duarte-Salles[8] · Clement Fraboulet[9] · Tanguy Le Carrour[10] · Spiros Denaxas[11] · Vaclav Papez[11] · Luis H. John[12] · Peter R. Rijnbeek[13] · Evan Minty[14] · Thamir M. Alshammari[15,16] · Rupa Makadia[1,2] · Clair Blacketer[1,2] · Frank DeFalco[1,2] · Anthony G. Sena[1,2] · Marc A. Suchard[2,17] · Daniel Prieto-Alhambra[16] · Patrick B. Ryan[1,2]

Accepted: 1 May 2022 / Published online: 2 June 2022
© The Author(s) 2022

Abstract

Introduction Vaccine-induced thrombotic thrombocytopenia (VITT) has been identified as a rare but serious adverse event associated with coronavirus disease 2019 (COVID-19) vaccines.

Objectives In this study, we explored the pre-pandemic co-occurrence of thrombosis with thrombocytopenia (TWT) using 17 observational health data sources across the world. We applied multiple TWT definitions, estimated the background rate

frontiers in Pharmacology

ORIGINAL RESEARCH
published: 24 November 2021
doi: 10.3389/fphar.2021.773875

Bias, Precision and Timeliness of Historical (Background) Rate Comparison Methods for Vaccine Safety Monitoring: An Empirical Multi-Database Analysis

OPEN ACCESS

Edited by:
Emanuel Raschi,
University of Bologna, Italy

Reviewed by:
Rosa Gini,
ARS Toscana, Italy

Xintong Li[1], Lana YH Lai[2], Anna Ostropolets[3], Faaizah Arshad[4], Eng Hooi Tan[1], Paula Casajust[5], Thamir M. Alshammari[6], Talita Duarte-Salles[7], Evan P. Minty[8], Carlos Areia[9], Nicole Pratt[10], Patrick B. Ryan[11,12], George Hripcsak[3,13], Marc A. Suchard[4,11], Martijn J. Schuemie[3,11,12*] and Daniel Prieto-Alhambra[9,14]

[1]Centre for Statistics in Medicine, NDORMS, University of Oxford, Oxford, United Kingdom, [2]School of Medical Sciences, University of Manchester, Manchester, United Kingdom, [3]Department of Biomedical Informatics, Columbia University, New York, NY, United States, [4]Department of Biostatistics, University of California, Los Angeles, California, United States, [5]Real-World Evidence, Real-World Solutions, IQVIA, Barcelona, Spain, [6]Clinical Research Centre, Clinical and Health Sciences, University of Nice and Informatics, New York, NY, United States, [7]Medical Informatics Services, NewYork-Presbyterian Hospital, New York, NY, United States, [8]Medical Informatics Services, Erasmus Medical Center

JMIR PUBLIC HEALTH AND SURVEILLANCE — Ostropolets et al

Original Paper

Characterizing Anchoring Bias in Vaccine Comparator Selection Due to Health Care Utilization With COVID-19 and Influenza: Observational Cohort Study

Anna Ostropolets[1], MD; Patrick B Ryan[2], PhD; Martijn J Schuemie[2], PhD; George Hripcsak[1,3], MD

[1]Department of Biomedical Informatics, Columbia University Irving Medical Center, New York, NY, United States
[2]Epidemiology Analytics, Janssen Research and Development, Titusville, NJ, United States
[3]Medical Informatics Services, New York-Presbyterian Hospital, New York, NY, United States

Corresponding Author:
George Hripcsak, MD

Leadership within OHDSI

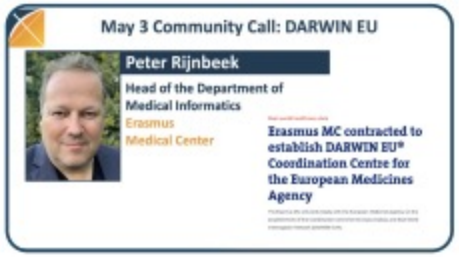
- Leadership is the foundation of an initiative
  - OHDSI has been hugely successful
  - A successful group seems to lead itself
  - Leaders vs bosses: inspire, set example, give credit
- Diverse group: pull from world, field, career stage
- For transparency, shifted to formal workgroups
  - Leadership summits and workshops (Paul Nagy and colleagues)
- Titan Awards upcoming
- **We are looking to find and grow leaders**
  - Especially junior

Leadership of OHDSI

- Known for CDM, build evidence reputation
  - Producing the best evidence
- Pull research to be more rigorous
  - Pull towards yourself, push away from yourself
- Set the standard for rigorous research
  - Stay tuned for plenary
- And produce useful evidence

How do you get involved?

Community calls:



October 18:
Welcome to OHDSI

October 25:
Future directions

How Can You Join The Journey?

Our community has set both the foundation and the highest of standards for global collaboration around observational research. We continue to make real differences in healthcare, and we are doing it through transparent and reproducible science. We also recognize that there is so much more to be done, and so much more that we can do.

If you are inspired by what you read in this book, if you want to learn more about methods research or open-source development, if you have a clinical question you believe needs answering, or if you want to join a community of people dedicated to the team sport of observational health data sciences and informatics, we have a place for you.

How can you get started?

Step One: Join The OHDSI Forums (forums.ohdsi.org)

Connect with other OHDSI collaborators on our community forums and start discussing how you can help us inform medical decision-making, or simply follow discussions that are interesting to you and learn about the work happening within our global community.

Step Two: Join Our Workgroups & MS Teams Environment (ohdsi.org/ohdsi-workgroups)

OHDSI has 27 active workgroups that always seek new collaborators. Our workgroups present opportunities for all community members to find a home for their talents and passions, and a place to make meaningful contributions. Our workgroups collaborate inside the OHDSI MS Teams environment; a form to join our Teams environment is available here: bit.ly/Join-OHDSI-Teams.

Step Three: Join Our Community Calls (ohdsi.org/community-calls/)

Join collaborators around the world each week during our OHDSI Community Call, held Tuesdays at 11 am ET within our Teams environment. Following weekly updates, we have a variety of call formats, including research presentations, workgroup updates, discussions, debates and more. These calls are recorded, and you can access them (as well as the meeting link) at our Community Calls page.

Step Four: Continue To Learn About OHDSI

Learn about OHDSI tools and research processes in a variety of ways.

- The Book of OHDSI (which is also translated into both Korean and Chinese) is a community-developed resource with information for every step of your journey: ohdsi.github.io/TheBookOfOhdsi

- Check out the EHDEN Academy, a set of free, on-demand training and development courses. These are open to anybody, but we always encourage new OHDSI collaborators to use this resource to learn about best practices towards our mission of improving health by empowering a community to collaboratively generate evidence that promotes better health decisions and better care: academy.ehden.eu

- Our OHDSI News page keeps you informed of recent news, publications, upcoming studies and more, while also profiling collaborators and providing other updates: ohdsi.org/ohdsi-news-updates

- Check out the OHDSI YouTube page (youtube.com/c/OHDSI) for many community-developed learning resources, including tutorials, research presentations and more. Follow OHDSI on both Twitter (@OHDSI) and LinkedIn (OHDSI) to keep updated on community research and follow the #OHDSISocialShowcase to see the research shared at our annual symposia.

Join The Journey

Your journey with OHDSI has started. Your interest in our global community is the first step in making a difference in global health. There is no limit to the impact you can make, and you can do so in a supportive, positive and fun environment. We invite you to search our website, post to the forum, join us in Teams, check out our GitHub (github.com/OHDSI), or reach out to us over email (contact@ohdsi.org).

Thank you for Joining The Journey with OHDSI!

Main Conference Agenda this morning

OHDSI
Observational Health Data Sciences and Informatics

OHDSI 2022 Symposium
Oct. 14-16, 2022
Bethesda North Marriott Hotel & Conference Center

Main Conference Agenda • Oct. 14

7:30 am - 8:30 am *Ballroom AE Foyer*	Registration and Lite Breakfast
9:00 am - 10:00 am *Ballroom DE*	**State of the Community** George Hripcsak, Columbia University **Safety Monitoring of COVID-19 Vaccines within the FDA BEST Initiative** Patricia Lloyd, US Food and Drug Administration **Presentation of 2020, 2021 Titan Awards** George Hripcsak, Columbia University/ Patrick Ryan, Johnson & Johnson, Columbia University
10:00 am - 10:45 am *Ballroom DE*	**Workgroup Connections** • *WG leads will be distributed across the venue and available for networking to share activities & progress, and connect for future collaborations* **OHDSI Meet The Mentors** *(Ballroom Side Foyer)*
10:45 am - 12:15 pm *Ballroom DE*	**Plenary: Objective Diagnostics: A pathway to provably reliable evidence** Martijn Schuemie, Johnson & Johnson
12:15 pm - 1:00 pm *Ballroom Foyer*	**Buffet Lunch** • *buffet in exhibitor space*

Main Conference Agenda this afternoon

1:00 pm - 2:00 pm *Ballroom DE*	**Presentations: OHDSI support for regulatory authorities** moderator: Jody-Ann McLeggon, Columbia University • *"US FDA/CBER: Performance of vaccine safety surveillance methods" Fan Bu, UCLA* • *"Korea Ministry of Food and Drug Safety: Replication of clinical trials in electronic health records" Seng Chan You, Yonsei University* • *"European Medicines Agency: DARWIN-EU" Peter Rijnbeek, Erasmus MC*
2:00 pm - 3:00 pm *Ballroom ABC*	**Collaborator Showcase, Round 1** • *Poster presentations with poster walks* • *Software demonstrations* • *Exhibitors (Foyer)*
3:00 pm - 4:00 pm *Ballroom DE*	**Collaborator Showcase Lightning Talks** moderator: Kristin Kostka, Roux Institute at Northeastern University • *"Disambiguation of ICPC codes using free-text and active learning to improve concept mappings" Tom Seinen, Erasmus MC* • *"OHDSI Phenotype Phebruary: lessons learned" Azza Shoaibi, Johnson & Johnson*

Download the full agenda at:

https://www.ohdsi.org/ohdsi2022symposium/

3:00 pm - 4:00 pm *Ballroom DE* *(continued)*	• *"Reduce, Reuse, & Recycle: Going Green with Atlas Reusables" Ajit Londhe, Amgen* • *"Best practices for prognostic model development using observational health data: a scoping review" Cynthia Yang, Erasmus MC* • *"Machine Learning for Predicting Patients at Risk of Prolonged Opioid Use Following Surgery" Behzad Naderalvojoud, Stanford University* • *"When does statistical equality meet health equity: developing analytical pipelines to compare associational and causal fairness in their application to EHR data" Linying Zhang, Columbia University* • *"Analyzing the Effect of Hypertension on Retinal Thickness Using Radiology Common Data Model (R-CDM)" Chul Hyoung Park, Ajou University* • *"Multinational Patterns of Second-line Anti-hyperglycemic Drug Initiation: A LEGEND-T2DM Study" Lovedeep Dhingra, Yale University*
4:00 pm - 5:00 pm *Ballroom ABC*	**Collaborator Showcase, Round 2** • *Poster presentations with poster walks* • *Software demonstrations* • *Exhibitors (Foyer)*
5:00 pm - 6:00 pm *Ballroom DE*	**Closing Talk: Building A Healthier World Together** Patrick Ryan, Johnson & Johnson, Columbia University • *2022 Titan Awards* • *Group photo at conclusion*
6:00 pm - 7:00 pm *Ballroom ABC*	**Networking Reception**

Full-day Tutorial – October 15
An Introductory Journey From Data To Evidence

Time	Title	Faculty
7:30 am - 8:30 am	Registration/Lite Breakfast (White Oak Foyer)	
8:30 am - 9:00 am	Overview of the OHDSI Journey: where are we going?	Patrick Ryan
9:00 am - 9:50 am	OMOP Common Data Model and vocabulary	Clair Blacketer
9:50 am - 10:00 am	Energy Break	
10:00 am - 10:50 am	ETL a source database into OMOP CDM	Melanie Philofsky
10:50 am - 11:00 am	Energy Break	
11:00 am - 11:50 am	Creating Cohort Definitions	Asieh Golozar
11:50 am - 12:30 pm	Buffet Lunch	
12:30 pm - 1:20 pm	Phenotype Evaluation	Gowtham Rao
1:20 pm - 1:30 pm	Energy Break	
1:30 pm - 2:20 pm	Characterization	Kristin Kostka
2:20 pm - 2:30 pm	Energy Break	
2:30 pm - 3:20 pm	Estimation	Martijn Schuemie
3:20 pm - 3:30 pm	Energy Break	
3:30 pm - 4:20 pm	Prediction	Jenna Reps
4:20 pm - 5:00 pm	Recap of the OHDSI Journey: Where do we go from here?	George Hripcsak

Workgroup activities – October 15-16

Saturday, October 15	
Start Time (ET)	End Time (ET)
800	900
900	1000
1000	1100
1100	1200
1200	1300
1300	1400
1400	1500
1500	1600
1600	1700
1700	1800
1800	1900
Sunday, October 16	
800	900
900	1000
1000	1100
1100	1200
1200	1300
1300	1400
1400	1500
1500	1600
1600	1700

<table>
<tr><td rowspan="6">Tutorial: An Introductory Journey From Data to Evidence</td><td rowspan="2">HADES Hack-a-thon: Part 1</td><td rowspan="2"></td><td>FHIR-OMOP: Terminologies Subgroup, Part 1</td></tr>
<tr><td rowspan="2">Oncology WG</td><td>FHIR-OMOP: Increasing the Value of Data Through a Rich Set of Attributes</td></tr>
<tr><td>Lunch</td><td>Lunch</td><td>Lunch</td></tr>
<tr><td rowspan="3">Methods Research (PLE/PLP)</td><td>Oncology WG (continued)</td><td>FHIR-OMOP: Data Model Harmonization Subgroup</td></tr>
<tr><td>Natural Language Processing</td><td>FHIR-OMOP: Oncology Subgroup</td></tr>
<tr><td colspan="2"></td><td>FHIR-OMOP: Terminologies Subgroup, Part 2</td></tr>
</table>

<table>
<tr><td colspan="2" rowspan="2">All-Hands Workgroup Meeting</td><td colspan="2" rowspan="2"></td></tr>
<tr></tr>
<tr><td colspan="2">Lunch</td><td>Lunch</td><td>Lunch</td></tr>
<tr><td rowspan="2">CDM and Data Quality</td><td rowspan="2">HADES Hack-a-thon: Part 2</td><td>Education</td><td rowspan="2">Phenotype Evaluation</td></tr>
<tr><td>Health Equity</td></tr>
</table>

Thank you

Safety Monitoring of COVID-19 Vaccines
FDA BEST Initiative

2022 OHDSI Symposium
October 14, 2022

Patricia Lloyd, PhD, ScM
Health Statistician
Office of Biostatistics and Pharmacovigilance
Center for Biologics Evaluation and Research
US Food and Drug Administration

Disclaimer

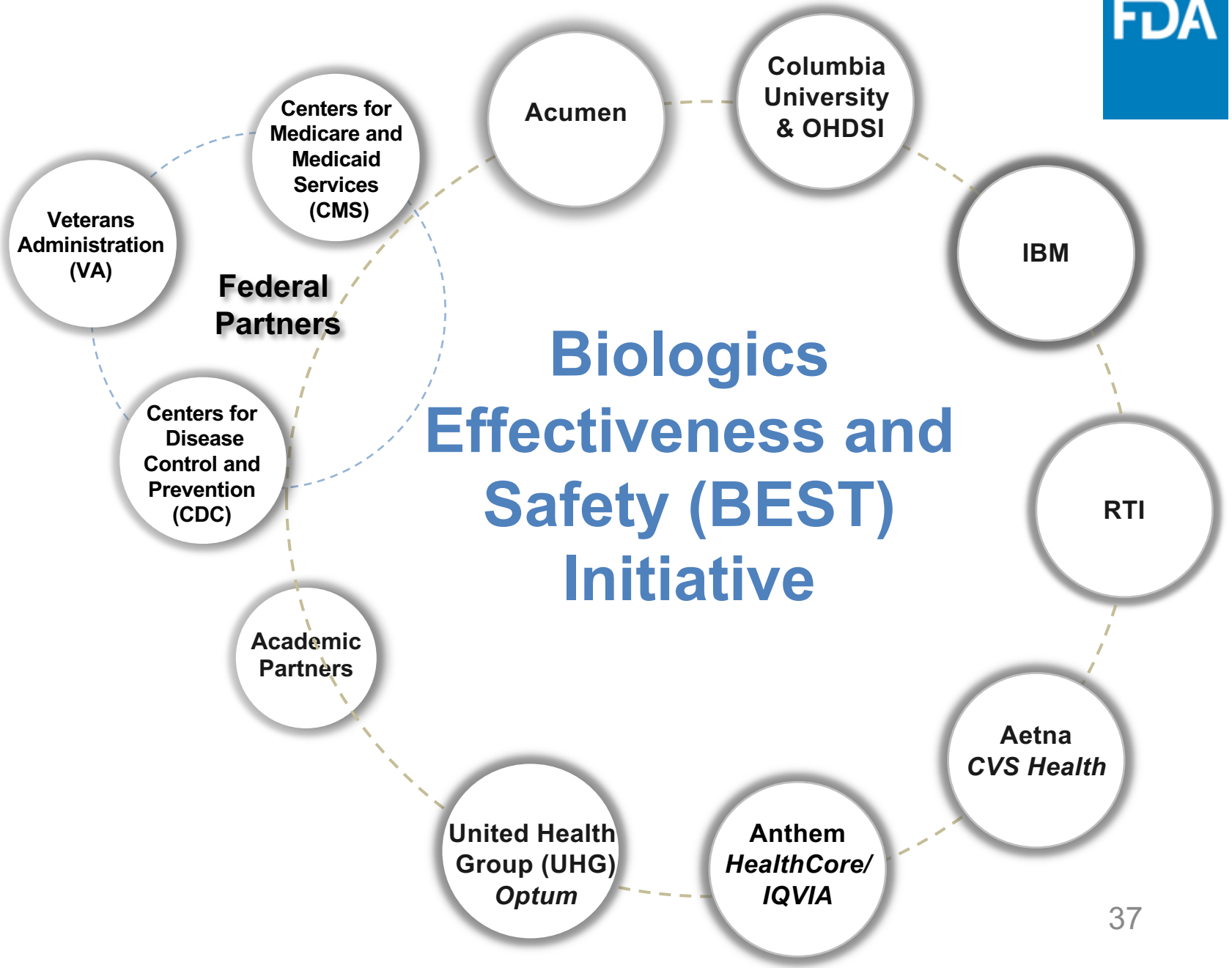
This presentation reflects the views of the authors and should not be construed to represent views or policies of the U.S. Food and Drug Administration.

CBER Regulated Products

- Vaccines (preventative and therapeutic)
- Blood (components and derived)
- Human Tissues and Cellular Products
- Gene Therapies
- Xenotransplantation Products

Center for Biologics Evaluation and Research (CBER) regulates biologic products[36]

FDA CBER Active Surveillance Program Collaborative

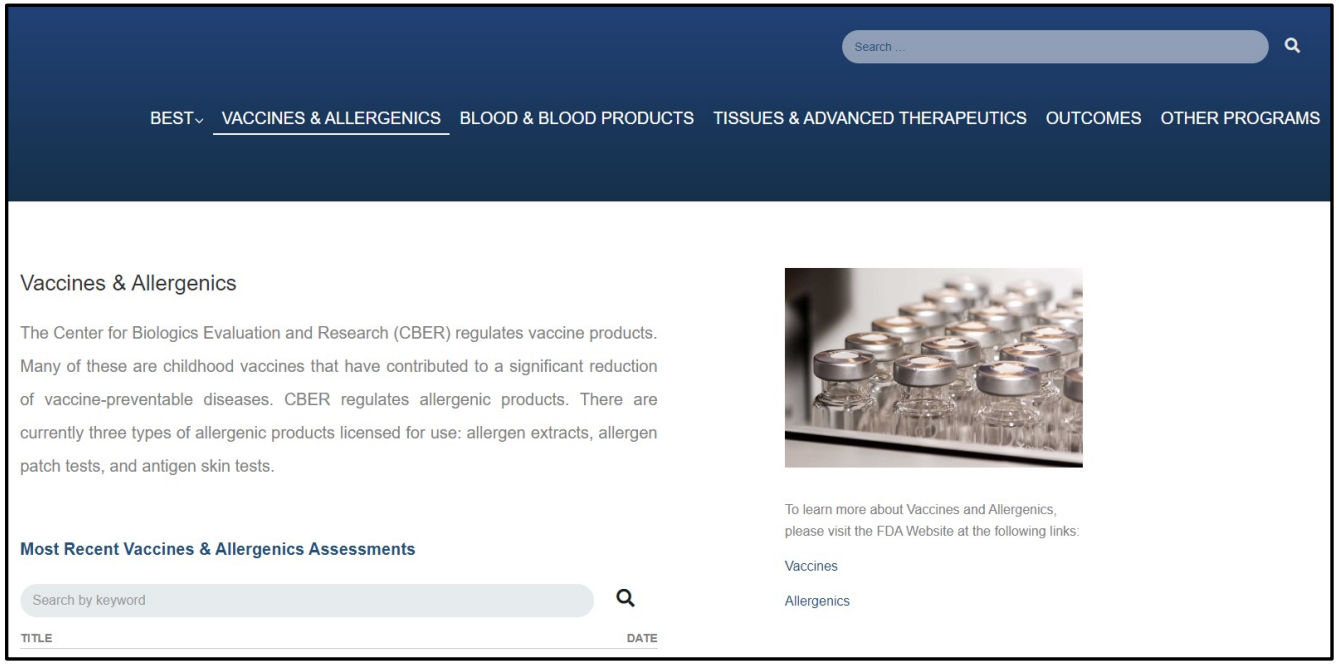


BEST Data Sources

BEST Initiative Data Source*	Database Type	No. Patients Covered (Millions)	Time Period Covered
CMS – Medicare	Claims	105	2005 - present
MarketScan Commercial and Medicare Supplemental	Claims	254	1999 - 2019
MarketScan Medicaid	Claims	48	1999 - 2019
Blue Health Intelligence	Claims	33.6	2012 - present
Optum – Adjudicated	Claims	66	1993 - present
Optum – Pre adjudicated	Claims	22	2017 - present
HealthCore	Claims	76	2006 - present
CVS Health	Claims	26	2014 - present
OneFlorida Clinical Research Consortium – Medicaid	Claims	6.7	2012 - present
OneFlorida Clinical Research Consortium – EHR	EHR	5.6	2012 – present
Optum EHR	EHR	102	2007 - 2020
MedStar Health Research Institute	EHR	6.0	2009 - present
PEDSnet	EHR	6.2	2009 - present
IBM CED	Linked EHR Claims	5.4	2000 - present
Optum Integrated Claims – EHR	Linked EHR Claims	25	2007 - 2020
OneFlorida Clinical Research Consortium – Linked EHR Claims	Linked EHR Claims	1.5	2012 - present

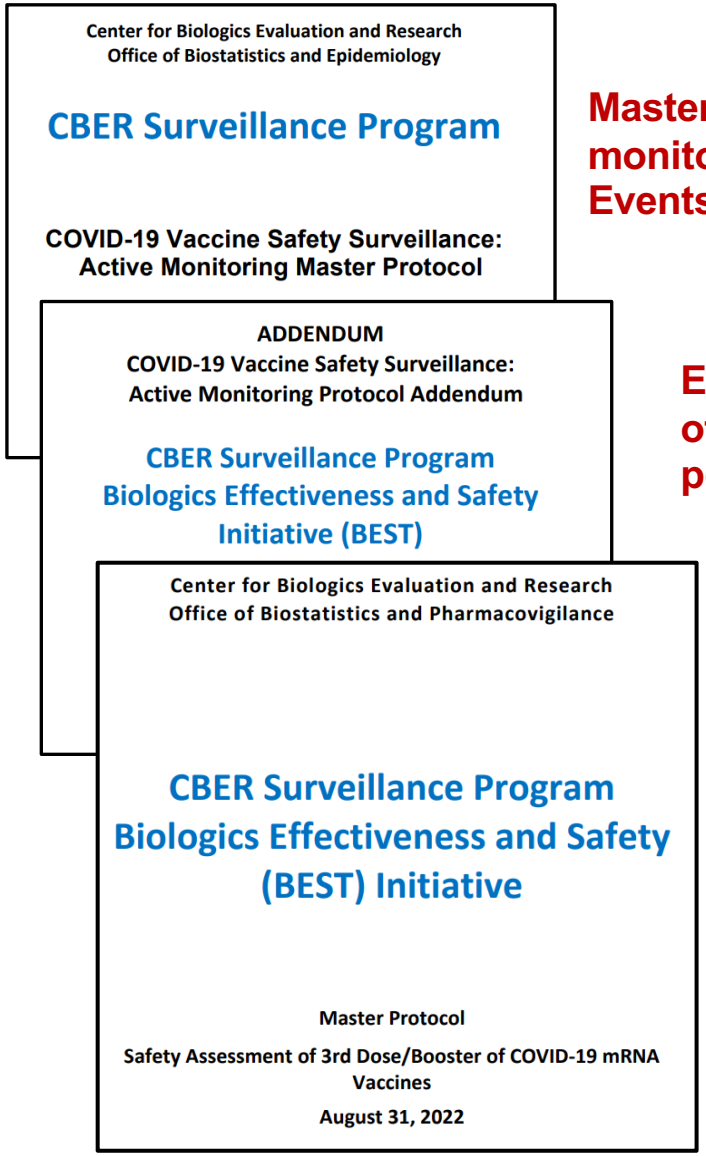
*Data lag varies for different databases from a few days to a few months.

COVID-19 Vaccines Safety Signal Detection



https://bestinitiative.org/vaccines-and-allergenics

BEST Program website provides the active monitoring master protocol and related addendums.



Master Protocol for monitoring Adverse Events (AEs)

Expands monitoring of AEs to pediatric population

Protocol for the 3rd dose/Booster study of COVID-19 mRNA vaccines

COVID-19 Vaccine Safety Monitoring

- **FDA-CMS Medicare**
  - >92% of US elderly use Medicare
  - Data cover very large population of >50 million US beneficiaries ≥ 65 years of age
  - Consists of claims data with access to medical charts

- **FDA Biologics Effectiveness and Safety (BEST) Initiative**
  - Use of commercial claims data for vaccine safety:
    - 3 major partners: Optum, CVS Health, HealthCore
  - Data includes individuals aged 0 – 64 years
  - Emphasis on detection of rare vaccine AEs (<1/100,000 doses)

COVID-19 Vaccine Safety Monitoring

List of Potential Adverse Events*

Adults
Acute Myocardial Infarction (AMI)
Anaphylaxis
Appendicitis
Disseminated Intravascular Coagulation (DIC)
Deep Vein Thrombosis (DVT)
Bell's Palsy
Encephalomyelitis/Encephalitis
Guillain-Barré Syndrome (GBS)
Hemorrhagic Stroke
Myocarditis/Pericarditis
Narcolepsy
Non-hemorrhagic Stroke (NHS)
Pulmonary Embolism (PE)
Transverse Myelitis
Immune Thrombocytopenia (ITP)
Thrombosis with Thrombocytopenia Syndrome (TTS) (unusual, common site)

Pediatrics	
Acute Myocardial Infarction (AMI)	Seizures
Anaphylaxis	Kawasaki Disease
Appendicitis	Multisystem Inflammatory Syndrome in children (MIS-C)
Disseminated Intravascular Coagulation (DIC)	
Deep Vein Thrombosis (DVT)	
Bell's Palsy	
Encephalomyelitis/Encephalitis	
Guillain-Barré Syndrome (GBS)	
Hemorrhagic Stroke	
Myocarditis/Pericarditis	
Narcolepsy	
Non-hemorrhagic Stroke (NHS)	
Pulmonary Embolism (PE)	
Transverse Myelitis	
Immune Thrombocytopenia (ITP)	
Thrombosis with Thrombocytopenia Syndrome (TTS) (unusual, common site)	

* These AESIs have not been associated with COVID-19 vaccines based on available pre-licensure evidence.

COVID-19 Vaccine Safety Monitoring

Signal detection and/or Rapid Cycle Analysis (RCA)

- Primary series RCA (Medicare ≥ 65 years); initiation date: **Feb 2021**
- Primary series RCA (12-64 years); initiation date: **Jun 2021**
- Primary series pediatric RCA (6 month-17 years); initiation date: **Jun 2022**
- Monovalent Booster Analysis (Medicare ≥ 65 years); initiation date: **Mar 2022**
- Monovalent Booster Analysis (18-64 years); initiation date: **Jun 2022**
- Bivalent Booster RCA; initiation date: **Nov 2022**

COVID-19 Vaccine Safety Monitoring

Signal evaluation and/or fully adjusted studies

- Vascular outcomes, primary series, self-controlled design; completion date: **Aug 2022**
- Myocarditis/pericarditis; completion date: **Dec 2021**
- Monovalent Booster Self-Controlled Case Series (SCCS); *In progress*

COVID-19 Vaccine Safety Studies

Key outcomes and communication

Vascular outcomes (RCA)[1]

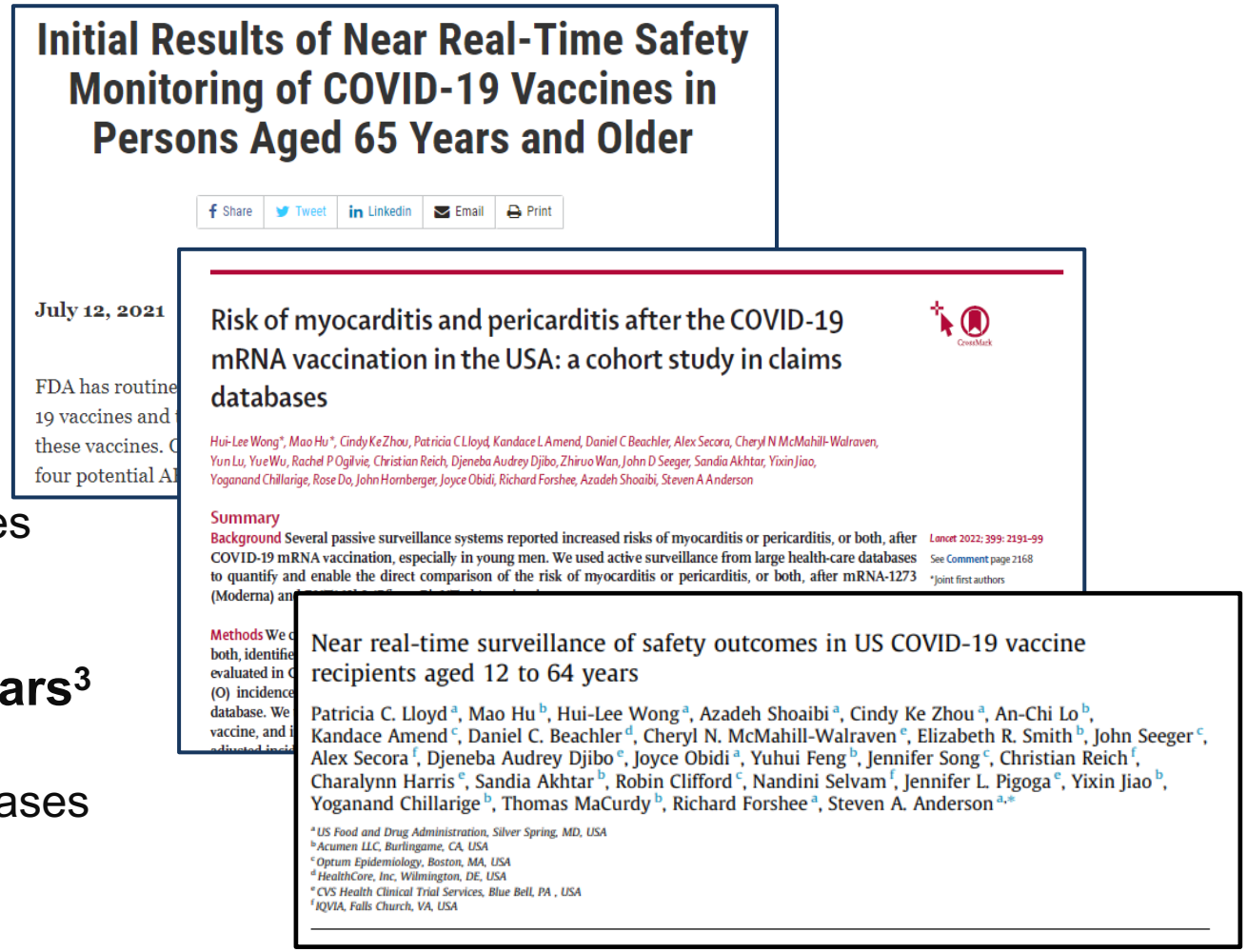
- Four potential AESIs detected
- Adults 65 years and older
- Post-vaccination with Pfizer-BioNTech COVID-19 vaccines
- FDA safety communication – **Jul 2021**

Myocarditis/Pericarditis[2]

- Potential signal in young, male adults
- Post-vaccination with mRNA COVID-19 vaccines
- Study completion – **Dec 2021**

RCA in adolescents and adults aged 12-64 years[3]

- 17 outcomes monitored in 3 databases
- Myocarditis/pericarditis signaled in 2 of 3 databases
- Anaphylaxis signaled in all databases
- Study completion – **Apr 2022**



Initial Results of Near Real-Time Safety Monitoring of COVID-19 Vaccines in Persons Aged 65 Years and Older

Share Tweet LinkedIn Email Print

July 12, 2021

FDA has routine
19 vaccines and
these vaccines.
four potential A

Risk of myocarditis and pericarditis after the COVID-19 mRNA vaccination in the USA: a cohort study in claims databases

Hui-Lee Wong*, Mao Hu*, Cindy Ke Zhou, Patricia C Lloyd, Kandace L Amend, Daniel C Beachler, Alex Secora, Cheryl N McMahill-Walraven, Yun Lu, Yue Wu, Rachel P Ogilvie, Christian Reich, Djeneba Audrey Djibo, Zhiruo Wan, John D Seeger, Sandia Akhtar, Yixin Jiao, Yoganand Chillarige, Rose Do, John Hornberger, Joyce Obidi, Richard Forshee, Azadeh Shoaibi, Steven A Anderson

Summary

Background Several passive surveillance systems reported increased risks of myocarditis or pericarditis, or both, after COVID-19 mRNA vaccination, especially in young men. We used active surveillance from large health-care databases to quantify and enable the direct comparison of the risk of myocarditis or pericarditis, or both, after mRNA-1273 (Moderna) an

Lancet 2022; 399: 2191–99
See Comment page 2168
*Joint first authors

Methods We
both, identifie
evaluated in
(O) incidence
database. We
vaccine, and i

Near real-time surveillance of safety outcomes in US COVID-19 vaccine recipients aged 12 to 64 years

Patricia C. Lloyd [a], Mao Hu [b], Hui-Lee Wong [a], Azadeh Shoaibi [a], Cindy Ke Zhou [a], An-Chi Lo [b], Kandace Amend [c], Daniel C. Beachler [d], Cheryl N. McMahill-Walraven [e], Elizabeth R. Smith [b], John Seeger [c], Alex Secora [f], Djeneba Audrey Djibo [e], Joyce Obidi [a], Yuhui Feng [b], Jennifer Song [c], Christian Reich [f], Charalynn Harris [e], Sandia Akhtar [b], Robin Clifford [c], Nandini Selvam [f], Jennifer L. Pigoga [e], Yixin Jiao [b], Yoganand Chillarige [b], Thomas MaCurdy [b], Richard Forshee [a], Steven A. Anderson [a,*]

[a] US Food and Drug Administration, Silver Spring, MD, USA
[b] Acumen LLC, Burlingame, CA, USA
[c] Optum Epidemiology, Boston, MA, USA
[d] HealthCore, Inc, Wilmington, DE, USA
[e] CVS Health Clinical Trial Services, Blue Bell, PA , USA
[f] IQVIA, Falls Church, VA, USA

1. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/initial-results-near-real-time-safety-monitoring-covid-19-vaccines-persons-aged-65-years-and-older
2. Wong, Hui-Lee et al., Risk of myocarditis and pericarditis after the COVID-19 mRNA vaccination in the USA: a cohort study in claims databases. The Lancet, Volume 399, Issue 10342, 2191 – 2199
3. Lloyd PC, Hu M, Wong HL, Shoaibi A, Ke Zhou C, Lo AC, Amend K, Beachler DC, McMahill-Walraven CN, Smith ER, Seeger J, Secora A, Audrey Djibo D, Obidi J, Feng Y, Song J, Reich C, Harris C, Akhtar S, Clifford R, Selvam N, Pigoga JL, Jiao Y, Chillarige Y, MaCurdy T, Forshee R, Anderson SA. Near real-time surveillance of safety outcomes in US COVID-19 vaccine recipients aged 12 to 64 years. Vaccine. 2022 Sep 27:S0264-410X(22)01167-7. doi: 10.1016/j.vaccine.2022.09.060. Epub ahead of print. PMID: 36195472; PMCID: PMC9513329.

Thank you

Website: https://bestinitiative.org/
Email: fdabest@fda.hhs.gov

Titans Awards 2020/2021

Titan Awards

- To recognize OHDSI collaborators (or collaborating institutions) for their contributions towards OHDSI's mission, the OHDSI Titan Awards were introduced at the 2018 Symposium and have been handed out at the U.S./Global Symposium each year since.
- Annually, community members are invited to nominate individuals or institutions they feel have made significant contributions towards advancing OHDSI's mission, vision and values.
- Once nominations are submitted, the OHDSI Titan Award Committee will select the award winners.

2020 Titan Awards

Clair Blacketer

Data Standards

Talita Duarte-Salles

Collaboration

Nicolas Thurin

Methods

Erasmus Medical Center

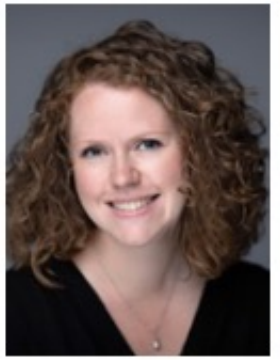
Support

Anthony Sena

Open-Source

Dani Prieto-Alhambra

Leadership



Jennifer Lane

Clinical

2021 Titan Awards

Maxim Moinat
Data Standards

Erica Voss
Collaboration

Yong Chen
Methods

Faaizah Arshad
Support

Ross Williams
Support

Adam Black
Open-Source

Mui Van Zandt
Leadership

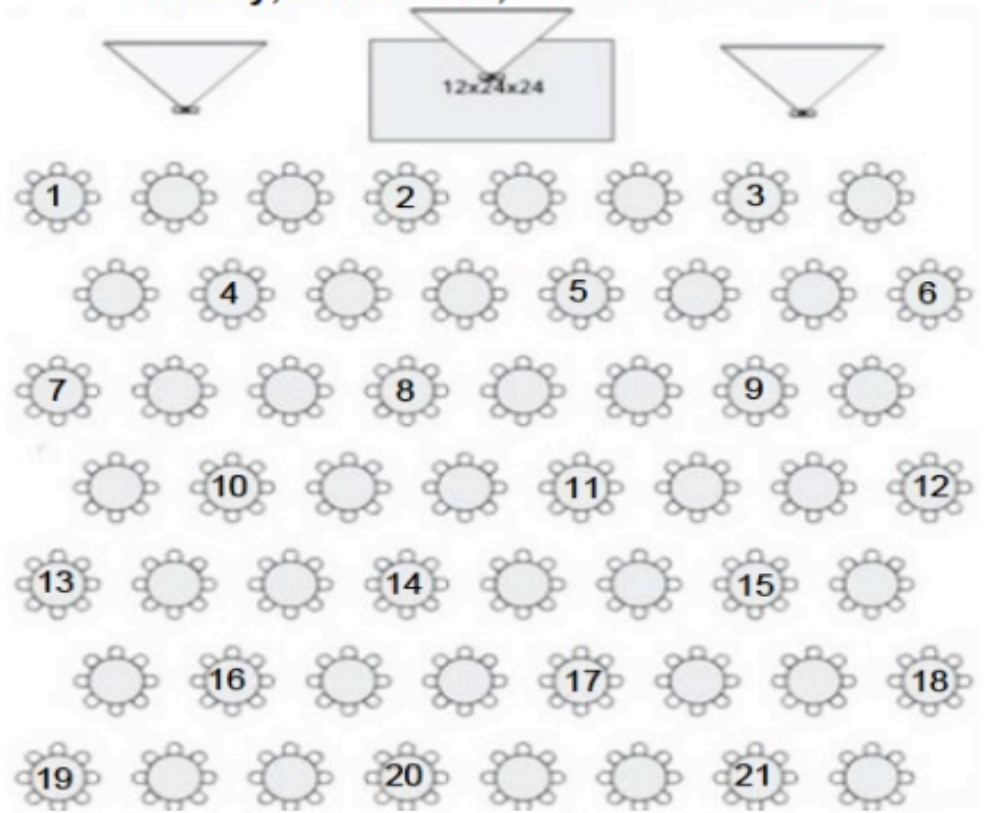
Asieh Golozar
Clinical

Congratulations to our 2022 Titan Award Nominees!

Thamir Alshammary • Juan Banda • Adam Black • Fan Bu • Montse Camprubi • Yong Chen • Marcel de Wilde • Frank DeFalco • Egill Fridgeirsson • Jamie Gilbert • Jake Gillberg • Jason Hsu • Nigel Hughes • Yu-Chuan Jack Li • Mik Kallfelz • Andy Kanter • Elisse Katzman • Chungsoo Kim • Greg Klebanov • Christopher Knoll • Kristin Kostka • Manlik Kwong • Christophe Lambert • Martin Lavallee • Jing Li • Xintong Li • Star Liu • Ajit Londhe • Aniek Markus • Evan Minty • Paul Nagy • Karthik Natarajan • Aki Nishimura • Anna Ostropolets • Melanie Philofsky • Gowtham Rao • Berta Raventos • Craig Sachson • Martijn Schuemie • Azza Shoaibi • Marc Suchard • Cynthia Sung • Joel Swerdel • May Terry • Don Torok • Cynthia Yang • Jacob Zelko • Center for Surgical Science Prediction study team • LEGEND-T2DM • N3C • Thrombosis with Thrombocytopenia phenotype project team • Vaccine Evidence Workgroup

OHDSI

Work Group Connections
Friday, October 14, 10:00AM-10:45AM



1 - Open-Source Community	2 - HADES	3 - ATLAS/WebAPI
4 - Common Data Model	5 - Vocabulary	6 - PatientLevelPrediction
7 - Medical Imaging	8 - Healthcare Systems	9 - FHIR & OMOP
10 - Phenotype Evaluation	11 - Education	12 - Medical Devices
13 - Oncology	14 - Eye Care & Vision	15 - NLP
16 - Early-Stage Researchers	17 - Psychiatry	18 - Health Equity
19 - Clinical Trials	20 - GIS	21 - Registry