OHDSI 2022
State of the Community

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Welcome!
OHDSI: Our Journey

Where the OHDSI Community Has Been And Where We Are Going

2022 edition

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

OHDSI Vocabularies By The Numbers
- 10,218,572 concepts
- 3,549,524 standard concepts
- 709,207 classification concepts
- 81,243,356 concept relationships
- 85,241,004 ancestral relationships
- 3,268,183 concept synonyms
- 135 vocabularies
- 42 domains

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 regional chapters

Africa
Current Participants: 66
Lead: Nega Gebreyesus

Australia
Current Participants: 74
Lead: Nicole Pratt

China
Current Participants: 228
Lead: Hua Xu

Europe
Current Participants: 321
Lead: Peter Rijnbeek

India
Current Participants: new
Lead: Swetha Kiranmayi Jakkuna

Japan
Current Participants: 49
Lead: Tatsuo Hiramatsu

Korea
Current Participants: 55
Lead: Seng Chan You

Singapore
Current Participants: 58
Lead: Mengling Feng

Taiwan
Current Participants: 71
Lead: Jason Hsu
OHDSI publications
22 pages highlighting the 475 publications from our community
OHDSI community dashboard: Publications

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 monthly.

Explore our community progress: [http://dash.ohdsi.org](http://dash.ohdsi.org)
OHDSI community dashboard: Educational content

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

Users by Year

Course Completions by Year
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 • Daily Threads & What We Learned

“Phenotype Phebrurary” 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.
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 DevCon 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 Khron 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 Khron Contributor Cohort, please check out the State of the Open Source Community presentation below.

State Of The Community Presentation
Panel: Putting The Pieces Together

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

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
Evaluating performance of vaccine evaluation methods

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


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

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

January 25 OHDSI Community Call
- Extracting OHDSI Concepts from Clinical Narratives for COVID
  - Dr. Hongtao Liu
  - Dr. Christopher G. Chute
  - Ruiyang Xiong
  - Professor of Health Informatics, University of Minnesota

March 8: CDM Workshop, Part 1
- Claire Blackmore
- Kristin Kestlo
- Maren Moeskert
- Yvonne Stoll

March 22: The OHDSI Vocabulary Journey
- Michael Killitz
- Patrick Ryan
- Orhelin Ketch

April 26 Community Call: Open Source Community
- Peter Woodall
- Scipri Oyer
- Oana Caciuba

May 3 Community Call: DAMMIN EU
- Team DAMMIN

May 17: OHDSI Debates
- Phenotypes Development
  - One-size-fits-all vs. tailored-per-databases
  - Brian Sandlass, Stanford University
- Study Diagnostics
  - Nice-to-have vs. essential requirements
  - Alex Koning, IBM

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, 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 (https://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 (https://groups.ohdsi.org)
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: https://docs.ohdsi.org

Step Three: Join Our Community Calls (https://community.ohdsi.org)
Join collaborator around the world each week during our OHDSI Community Call, held Tuesdays at 11 am ET within our Teams environment. Exploring monthly updates, we have a variety of call formats, including

October 18: Welcome to OHDSI
October 25: Future directions

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 our website, blog to the forum, join us in Taweek, check out our GitHub (https://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 2022 Symposium**  
Oct. 14-16, 2022  
Bethesda North Marriott Hotel & Conference Center

## Main Conference Agenda · Oct. 14

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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</thead>
<tbody>
<tr>
<td>7:30 am - 8:30 am</td>
<td>Registration and Lite Breakfast</td>
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</table>
| 9:00 am - 10:00 am | **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 | **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 | **Plenary: Objective Diagnostics: A pathway to provably reliable evidence**  
Martijn Schuemie, Johnson & Johnson |
| 12:15 pm - 1:00 pm | **Buffet Lunch**  
*buffet in exhibitor space* |
Main Conference Agenda this afternoon

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Details</th>
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<tbody>
<tr>
<td>1:00 pm - 2:00 pm</td>
<td>Presentations: OHDSI support for regulatory authorities</td>
<td>Moderator: Jody-Ann McLeggan, Columbia University</td>
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<td></td>
<td>• “US FDA/CBER: Performance of vaccine safety surveillance methods” Fan Bu, UCLA</td>
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<td>• “Korea Ministry of Food and Drug Safety: Replication of clinical trials in electronic health records” Seng Chan You, Yonsei University</td>
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<td>• “European Medicines Agency: DARWIN-EU” Peter Rijnbeek, Erasmus MC</td>
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<tr>
<td>2:00 pm - 3:00 pm</td>
<td>Collaborator Showcase, Round 1</td>
<td>Poster presentations with poster walks</td>
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<td>Software demonstrations</td>
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<td>Exhibitors (Foyer)</td>
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<tr>
<td>3:00 pm - 4:00 pm</td>
<td>Collaborator Showcase Lightning Talks</td>
<td>Moderator: Kristin Kostka, Roux Institute at Northeastern University</td>
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<td>“Disambiguation of ICPC codes using free-text and active learning to improve concept mappings” Tom Seinen, Erasmus MC</td>
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<td>“OHDSI Phenotype Phlebuary: lessons learned” Azza Shoaibi, Johnson &amp; Johnson</td>
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<tr>
<td>3:00 pm - 4:00 pm</td>
<td>• “Reduce, Reuse, &amp; Recycle: Going Green with Atlas Reusables” Ajit Londe, Amgen</td>
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<td>• “Best practices for prognostic model development using observational health data: a scoping review” Cynthia Yang, Erasmus MC</td>
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<td>• “Machine Learning for Predicting Patients at Risk of Prolonged Opioid Use Following Surgery” Behzad Naderalievjoud, Stanford University</td>
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<td>• “When does statistical equality meet health equity: developing analytical pipelines to compare association and causal inferences in their application to EHR data” Lining Zhang, Columbia University</td>
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<td>• “Analyzing the Effect of Hypertension on Retinal Thickness Using Radiology Common Data Model (R-CDM)” Chul Hyong Park, Ajou University</td>
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<td>• “Multinational Patterns of Second-line Anti-hypertensive Drug Initiation: A LEGEND-T2DM Study” Lovdeep Dhingra, Yale University</td>
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<tr>
<td>4:00 pm - 5:00 pm</td>
<td>Collaborator Showcase, Round 2</td>
<td>Poster presentations with poster walks</td>
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<td>Software demonstrations</td>
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<td>Exhibitors (Foyer)</td>
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<tr>
<td>5:00 pm - 6:00 pm</td>
<td>Closing Talk: Building A Healthier World Together</td>
<td>Patrick Ryan, Johnson &amp; Johnson, Columbia University</td>
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<td>2022 Titan Awards</td>
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<td>Group photo at conclusion</td>
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<tr>
<td>6:00 pm - 7:00 pm</td>
<td>Networking Reception</td>
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Download the full agenda at: https://www.ohdsi.org/ohdsi2022symposium/
# Full-day Tutorial – October 15

## An Introductory Journey From Data To Evidence

<table>
<thead>
<tr>
<th>Time</th>
<th>Title</th>
<th>Faculty</th>
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<tbody>
<tr>
<td>7:30 am - 8:30 am</td>
<td>Registration/Lite Breakfast (White Oak Foyer)</td>
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<tr>
<td>8:30 am - 9:00 am</td>
<td>Overview of the OHDSI Journey: where are we going?</td>
<td>Patrick Ryan</td>
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<tr>
<td>9:00 am - 9:50 am</td>
<td>OMOP Common Data Model and vocabulary</td>
<td>Clair Blacketer</td>
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<tr>
<td>9:50 am - 10:00 am</td>
<td>Energy Break</td>
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<tr>
<td>10:00 am - 10:50 am</td>
<td>ETL a source database into OMOP CDM</td>
<td>Melanie Philofsky</td>
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<td>10:50 am - 11:00 am</td>
<td>Energy Break</td>
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<td>11:00 am - 11:50 am</td>
<td>Creating Cohort Definitions</td>
<td>Asieh Golzar</td>
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<td>11:50 am - 12:30 pm</td>
<td>Buffet Lunch</td>
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<td>12:30 pm - 1:20 pm</td>
<td>Phenotype Evaluation</td>
<td>Gowtham Rao</td>
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<td>Energy Break</td>
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<td>1:30 pm - 2:20 pm</td>
<td>Characterization</td>
<td>Kristin Kostka</td>
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<td>2:20 pm - 2:30 pm</td>
<td>Energy Break</td>
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<td>2:30 pm - 3:20 pm</td>
<td>Estimation</td>
<td>Martijn Schuemie</td>
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<tr>
<td>3:20 pm - 3:30 pm</td>
<td>Energy Break</td>
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<tr>
<td>3:30 pm - 4:20 pm</td>
<td>Prediction</td>
<td>Jenna Reps</td>
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<tr>
<td>4:20 pm - 5:00 pm</td>
<td>Recap of the OHDSI Journey: Where do we go from here?</td>
<td>George Hripcsak</td>
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# Workgroup activities – October 15-16

<table>
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<tr>
<th>Time (ET)</th>
<th>Saturday, October 15</th>
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**Saturday, October 15**
- **Start Time (ET)**
  - 800
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  - 1800
  - 1900
- **End Time (ET)**
  - 900
  - 1000
  - 1100
  - 1200
  - 1300
  - 1400
  - 1500
  - 1600
  - 1700
  - 1800
  - 1900

**Sunday, October 15**
- **Start Time (ET)**
  - 800
  - 900
  - 1000
  - 1100
  - 1200
  - 1300
  - 1400
  - 1500
  - 1600
  - 1700
- **End Time (ET)**
  - 900
  - 1000
  - 1100
  - 1200
  - 1300
  - 1400
  - 1500
  - 1600
  - 1700

**Activities**
- **Tutorial: An Introductory Journey From Data to Evidence**
- **Methods Research (PLE/PLP)**
- **Natural Language Processing**
- **CDM and Data Quality**
- **Education**
- **Phenotype Evaluation**
- **All-Hands Workgroup Meeting**
- **FHIR-OMOP: Terminologies Subgroup, Part 1**
- **FHIR-OMOP: Increasing the Value of Data Through a Rich Set of Attributes**
- **FHIR-OMOP: Data Model Harmonization Subgroup**
- **FHIR-OMOP: Oncology Subgroup**
- **FHIR-OMOP: Terminologies Subgroup, Part 2**

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\begin{array}{c|c|c|c|c}
\text{Time (ET)} & \text{Event} & \text{Time (ET)} & \text{Event} \\
\hline
800 & \text{Start} & 900 & \text{End} \\
900 & \text{Tutorial} & 1000 & \text{Lunch} \\
1000 & \text{Methods Research} & 1100 & \text{Oncology WG (continued)} \\
1100 & \text{Natural Language Processing} & 1200 & \text{FHIR-OMOP: Data Model Harmonization Subgroup} \\
1200 & \text{Education} & 1300 & \text{FHIR-OMOP: Terminologies Subgroup, Part 2} \\
1300 & \text{Phenotype Evaluation} & 1400 & \\
1400 & & 1500 & \\
1500 & & 1600 & \\
1600 & & 1700 & \\
\end{array} \]
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
<table>
<thead>
<tr>
<th>BEST Initiative Data Source*</th>
<th>Database Type</th>
<th>No. Patients Covered (Millions)</th>
<th>Time Period Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMS – Medicare</td>
<td>Claims</td>
<td>105</td>
<td>2005 - present</td>
</tr>
<tr>
<td>MarketScan Commercial and Medicare Supplemental</td>
<td>Claims</td>
<td>254</td>
<td>1999 - 2019</td>
</tr>
<tr>
<td>MarketScan Medicaid</td>
<td>Claims</td>
<td>48</td>
<td>1999 - 2019</td>
</tr>
<tr>
<td>Blue Health Intelligence</td>
<td>Claims</td>
<td>33.6</td>
<td>2012 - present</td>
</tr>
<tr>
<td>Optum – Adjudicated</td>
<td>Claims</td>
<td>66</td>
<td>1993 - present</td>
</tr>
<tr>
<td>Optum – Pre adjudicated</td>
<td>Claims</td>
<td>22</td>
<td>2017 - present</td>
</tr>
<tr>
<td>HealthCore</td>
<td>Claims</td>
<td>76</td>
<td>2006 - present</td>
</tr>
<tr>
<td>CVS Health</td>
<td>Claims</td>
<td>26</td>
<td>2014 - present</td>
</tr>
<tr>
<td>OneFlorida Clinical Research Consortium – Medicaid</td>
<td>Claims</td>
<td>6.7</td>
<td>2012 - present</td>
</tr>
<tr>
<td>OneFlorida Clinical Research Consortium – EHR</td>
<td>EHR</td>
<td>5.6</td>
<td>2012 – present</td>
</tr>
<tr>
<td>Optum EHR</td>
<td>EHR</td>
<td>102</td>
<td>2007 - 2020</td>
</tr>
<tr>
<td>MedStar Health Research Institute</td>
<td>EHR</td>
<td>6.0</td>
<td>2009 - present</td>
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<tr>
<td>PEDSnet</td>
<td>EHR</td>
<td>6.2</td>
<td>2009 - present</td>
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<tr>
<td>IBM CED</td>
<td>Linked EHR Claims</td>
<td>5.4</td>
<td>2000 - present</td>
</tr>
<tr>
<td>OneFlorida Clinical Research Consortium – Linked EHR Claims</td>
<td>Linked EHR Claims</td>
<td>1.5</td>
<td>2012 - present</td>
</tr>
</tbody>
</table>

*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.
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*

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

* 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/Pericarditis²

- 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 years³

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

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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
Thank you

Website: https://bestinitiative.org/
Email: fdabest@fda.hhs.gov
Titans Awards 2020/2021
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

Nicolas Thurin
Methods

Anthony Sena
Open-Source

Talita Duarte-Salles
Collaboration

Erasmus Medical Center
Support

Dani Prieto-Alhambra
Leadership

Jennifer Lane
Clinical

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2021 Titan Awards

Maxim Moinat
Data Standards

Yong Chen
Methods

Adam Black
Open-Source

Asieh Golozar
Clinical

Erica Voss
Collaboration

Faaizah Arshad
Support

Ross Williams
Support

Mui Van Zandt
Leadership

www.ohdsi.org

#JoinTheJourney
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 Frideirsson • 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
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