How did OHDSI do in 2021?
OHDSI OKR end-of-year review

Patrick Ryan, PhD
Janssen Research & Development
Columbia University
<table>
<thead>
<tr>
<th>Rank</th>
<th>Highlight</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>Global symposium!!</td>
</tr>
<tr>
<td>6</td>
<td>Reproducibility workshop</td>
</tr>
<tr>
<td>6</td>
<td>CDM v5.4!</td>
</tr>
<tr>
<td>3</td>
<td>EUMAEUS</td>
</tr>
<tr>
<td>3</td>
<td>OHDSI contribution to background rates of AESI and to vaccine safety monitoring more widely</td>
</tr>
<tr>
<td>2</td>
<td>Working with EHDEN DPs</td>
</tr>
</tbody>
</table>
OHDSI’s mission

To improve health by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care
Why are you on the journey with OHDSI?

- 24  To collaborate with other researchers around the world
- 19  I want to generate evidence
- 16  To develop open source solutions to public health problems
- 11  For the data network
-  7  To be part of a community trying to make a positive impact
-  6  Improve the quality of epidemiological studies using observational data
-  5  To improve the way in which medical evidence is generated!
An organizing framework

• Objective: Ambitious goal of what is to be achieved
• Key Result: Specific measurable to benchmark and monitor how we get to the objective
Writing effective OKRs

• Objectives are the ‘Whats’. They:
  – Express goals and intents
  – Are aggressive yet realistic
  – Must be tangible, objective, and unambiguous; should be obvious to a rational
    observer whether an objective as been achieved
  – The successful achievement of an objective must provide clear value to the
    organization

• Key results are the ‘Hows’. They:
  – Express measureable milestones which, if achieved, will advance objective(s) in a
    useful manner to their constituents
  – Must describe outcomes, not activities
  – Must include evidence of completion. This evidence must be available, credible
    and easily discoverable.
<table>
<thead>
<tr>
<th>#</th>
<th>Objective</th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
<td>Generate and disseminate real-world evidence about the 3 substantial public health issues: COVID-19, type 2 diabetes, and health inequalities</td>
</tr>
<tr>
<td>18</td>
<td>Enable a community to generate real-world evidence using OHDSI tools and scientific best practices</td>
</tr>
<tr>
<td>10</td>
<td>Build an international medical product safety surveillance system that provides evidence about the incidence and risk of outcomes associated with drug exposure</td>
</tr>
<tr>
<td>3</td>
<td>I'd like to see OHDSI science impacting policy</td>
</tr>
<tr>
<td>0</td>
<td>Getting CDM v6 into broad use.</td>
</tr>
</tbody>
</table>
OKR review and grading

<table>
<thead>
<tr>
<th>Score range</th>
<th>Question to ask:</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.5 - 10</td>
<td>Are we being ambitious enough?</td>
</tr>
<tr>
<td>6.5 - 9.4</td>
<td>What have we learned?</td>
</tr>
<tr>
<td>4.0 - 6.4</td>
<td>How can we focus/help?</td>
</tr>
<tr>
<td>1.5 - 3.9</td>
<td>What do we need to change?</td>
</tr>
<tr>
<td>0 - 1.4</td>
<td>Should this remain an priority objective?</td>
</tr>
</tbody>
</table>
OHDSI in 2021

Objective: Generate and disseminate real-world evidence about the 3 substantial public health issues: COVID-19, type 2 diabetes, and health inequalities.

Key Results:
- 3 fully-reproducible study packages executed across at least 20 OHDSI data partners
- 10 publications accepted in journals with impact factor > 10
- 10 uses of OHDSI results by external stakeholders that demonstrate influence in policy or clinical decision-making
Key result 1: 3 fully-reproducible study packages executed across at least 20 OHDSI data partners

Calculating the background rates of adverse events of special interest (AESI) for the COVID vaccines

Evaluating the Sensitivity Of Prediction Model Development and Performance Due To Phenotypes Applied To COVID-19 VACCINES
Key result 2: 10 publications accepted in journals with impact factor > 10
Key result 3: 10 uses of OHDSI results by external stakeholders that demonstrate influence in policy or clinical decision-making.

CBER Surveillance Program

COVID-19 Vaccine Safety Surveillance: Active Monitoring Master Protocol

February 10, 2021

AstraZeneca’s COVID-19 vaccine: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets.

News 07/04/2021

EMA confirms overall benefit-risk remains.

Thrombosis with Thrombocytopenia: Post-Authorization Cases Reported after Janssen Vaccine and Background

非常的 rare, Rare, Uncommon, Common, Very Common

1. Cases, 10,000 people vaccinated: CDC (Apr 22)
2. Incidence based on COVID-19, Thrombocytopenia in 2018 from observational studies [worldwide, per million].

February 10, 2021
OHDSI in 2021

Objective:
Build an international medical product safety surveillance system that provides all stakeholders access to evidence about the incidence and risk of outcomes associated with drug exposure

Key Results:
– Population-level effect estimation and characterization results generated for 500 drugs and 500 outcomes across 20 databases
– 100 organizations with at least 1 active user
– 10 regulatory actions taken as a result of OHDSI system
System characteristics:
- Standardized procedures with defined inputs and outputs
- Analysis packages implementing scientific best practices consistently applied across all data partners, generating consistent output for network synthesis
- Reproducible outputs generated by open-source analysis libraries developed and validated with verifiable unit-test coverage
- Pre-specified and objective decision thresholds for go/no go criteria
- Measurable operating characteristics of system performance
Three potential use cases for the support to committees’ decision-making

From a regulatory perspective, RWE aims to support committees’ decision-making in three main areas:

<table>
<thead>
<tr>
<th>Use case objective</th>
<th>Support the planning &amp; validity of applicant studies</th>
<th>Understand clinical context</th>
<th>Investigate associations and impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use case category</td>
<td>Design and feasibility of planned studies</td>
<td>Disease epidemiology</td>
<td>Effectiveness and safety studies</td>
</tr>
<tr>
<td></td>
<td>Representativeness and validity of Completed studies</td>
<td>Clinical management &amp; drug utilisation</td>
<td>Impact of regulatory actions</td>
</tr>
</tbody>
</table>
Mapping regulatory use cases to evidence types

Support the planning & validity of applicant studies:
- Design and feasibility of planned studies
- Representativeness and validity of completed studies

Understand clinical context:
- Disease epidemiology
- Clinical management & drug utilisation

Investigate associations and impact:
- Effectiveness and safety studies
- Impact of regulatory actions

Clinical characterization: What happened to them?
- Who are the patients with disease eligible for treatment?
- Who are the patients exposed to those treatments?
- How often do outcomes occur amongst those patients?

Population-level effect estimation: What are the causal effects?
- Is the outcome causally related to exposure to treatment?
- How does the risk compare with alternative treatments?

Patient-level prediction: What will happen to me?
- Which risks can be actionably predicted with available data?
- Which patients are at highest risk of adverse events?

Questions that can be informed with real world evidence:
Level of proactivity in delivering real-world evidence

**Time-to-evidence**

- **~seconds**
  - Anticipatory
  - Generate and deliver insights without being asked; answer questions before requested by ‘pushing’ relevant pre-computed evidence to potential evidence consumers

- **~minutes**
  - Prepared
  - Produce pre-computed evidence to enable answer retrieval in ‘real time’ by qualified users when requested; standardized analysis packages executed across network generate results ‘at-scale’ across many target, outcome cohorts

- **~hours**
  - Responsive
  - Enable fast evidence generation by using interface that allow qualified users to set defined input parameters, execute standardized analyses, and view results upon request.

- **~days**
  - Enabled
  - Design and execute standardized analysis packages that apply validated statistical libraries with defined input parameters and fixed output to compile summary results across a network standardized to a common data model

- **~weeks, months, years**
  - Reactive Bespoke
  - Service bespoke project requests by convening team to align on problem statement, author protocol/analysis plan documents, implement statistical programming code to custom specification, execute analysis across databases, iteratively review results and request post hoc analyses, write summary of results as report, and deliver to decision-maker to ensure it meets their needs

**Standardized dissemination** +

**Standardized analysis configurations** +

**Standardized analysis tools** +

**Standardized data, network execution**
A 5-year vision for expanding the proactive use of real-world evidence across regulatory use cases

- Anticipatory
- Prepared
- Responsive
- Enabled
- Reactive Bespoke

Support the planning & validity of applicant studies

Understand clinical context

Investigate associations and impact

~seconds
~minutes
~hours
~days
~weeks, months, years

Today
2026
OHDSI in 2021

Objective:
Enable a community to generate real-world evidence using OHDSI tools and scientific best practices

Key Results:
– 100 organizations have a fully-operational technical infrastructure (CDM + ATLAS + HADES) sufficient to perform local analyses
– 1000 researchers complete RWE curriculum through EHDEN Academy
– 100 publications generated using and citing OHDSI tools
EHDEN Academy has made a solid start

- As of 7th December, >1830 participants/1467 enrolled with ~33% active in the last 14 days
  - 1822 badges (courses completed)
  - Major concentration in US, UK and Spain
  - Focus driven by EHDEN SME Learning Pathway in Europe

- 14 current courses available: ETL, tools & methods
- Curriculum roadmap developed to follow the research operation model with WP1, WP2, and WP4
- Non-expert course led by European Patients Forum
- Introduction to Data Quality launched prior to GAM#6

We are now leading the OHDSI Education WG:
- Strategy development
- Collaborating with educational initiatives worldwide
- Audit and inventory of OHSI resources
- Development of Learning Pathways

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90 Day all-cause mortality can be predicted following a total knee replacement: an international, network study to develop and validate a prediction model.

Williams RD, Reps JM; OHDSI/EHREN Knee Arthroplasty Group. Rijnbeek PR, Ryan PB, Pinto-Alhambra D.


PMID: 34070731


Pedrares MC, Garcia N, Rubio P, Cruz JL, Bernal JL, Serrano P.


PMID: 34795096

Transfer of Clinical Drug Data to a Research Infrastructure on OMOP - A FAIR Concept.

Raimer E, Zoch M, Wilhelm M, Sedlmayr M, Bathelt F.


PMID: 34795062
**OHDSI Working Groups**

OHDSI’s central mission is to improve health by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care. We work towards that goal in the areas of data standards, methodological research, open-source analytics development, and clinical applications.

Our 27 Working Groups present opportunities for all community members to find a home for their talents and passions, and make meaningful contributions. We are always looking for new collaborators.

See an area where you want to contribute? Please Join The Journey!

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**ATLAS**
- Current Participants: 56
- Lead: Anthony Sana

**Clinical Trials**
- Current Participants: 111
- Leads: Mike Hanley, Lin Zhan

**Common Data Model**
- Current Participants: 261
- Lead: Clair Blacketer

**Data Quality Dashboard Development**
- Current Participants: 50
- Lead: Clair Blacketer

**Early-Stage Researchers**
- Current Participants: 44
- Leads: Farah Amrashad, Rosa Williams

**Education**
- Current Participants: 31
- Lead: Nigel Hughes

**Electronic Health Record (EHR) ETL**
- Current Participants: 169
- Lead: Melanie Philipp

**Geographic Information System (GIS)**
- Current Participants: 56
- Leads: Robert Miller, Andrew Williams

**HADES (Health Analytics Data-to-Evidence Suite)**
- Current Participants: 120
- Lead: Martin Schulmeister

**Health Equity**
- Current Participants: 87
- Lead: Jake Gilberg

**Latin America**
- Current Participants: 15
- Lead: Jesus Posada

**Medical Devices**
- Current Participants: 52
- Leads: Vyacheslav Kuzer, Adiyah Lin

**Natural Language Processing**
- Current Participants: 226
- Lead: Hua Xu

**OHDSI Asia-Pacific (APAC)**
- Current Participants: 46
- Lead: Mui Van Zandt

**OHDSI APAC Steering Committee**
- Current Participants: 39
- Lead: Mui Van Zandt

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**OHDSI Regional Chapters**

An OHDSI regional chapter represents a group of OHDSI collaborators located in a geographic area who wish to hold local networking events and meetings to address problems specific to their geographic location.

- **Africa**
  - Current Participants: 17
  - Lead: Negar Golshayes

- **Australia**
  - Current Participants: 36
  - Lead: Nicole Pretz

- **China**
  - Current Participants: 163
  - Lead: Huawei

- **Europe**
  - Current Participants: 135
  - Lead: Peter Rijith

- **Japan**
  - Current Participants: 19
  - Lead: Tatsuo Hiramatsu

- **Korea**
  - Current Participants: 36
  - Lead: Seong Chan You

- **Singapore**
  - Current Participants: 30
  - Lead: Mengling Peng

- **Taiwan**
  - Current Participants: 45
  - Lead: Jason Hse
Common Data Model workgroup

Develop and Promote Community Adoption of a New CDM Version

• KR1: Collate a list of all additions and/or changes to be made to a new CDM Version by Q1
• KR: 100% agreement on new CDM Version from all affected workgroups by Q2
• KR: Release DDLs for new CDM Version by Q3

Thanks Clair Blacketer!
Perform the methods research required to generate reliable evidence on the effects of COVID vaccines from observational data

• Establish 1 research agenda that specifies knowledge gaps of interest to focus on with input from internal and external collaborators.
• Perform methods research, resulting in at least 5 submitted papers.
• Observe impact of this research in the design decisions of at least 1 internal study, 1 external study, and 1 study by a regulator.

Thanks Martijn Schuemie!
Clinical trials workgroup

Objective:
- Our use case is converting clinical trial data in CDISC SDTM format to OMOP CDM to optimize trial planning and reusability. Our proposal covers eight main topics with insufficient support in the OMOP CDM and Standardized Vocabularies. They include introducing new concepts and modifiers but no new CDM tables. Furthermore, we guide ETL developers when dealing with some data that is more complicated or specific scenarios that may be present in clinical trial submitted datasets (e.g., non-unique subject ids). Finally, it aligns with OMOP CDM v6 and the Oncology extension, with v5.3.1 backward compatibility.

Key Results:
- Drafted initial recommendations and best practices using limited synthetic SDTM datasets (8)
- Obtained agreement with Vivli and C-Path to get access to additional real world SDTM studies (8)
- Expanded the team with varying expertise and interest (7)

Thanks Mike Hamidi!
### Health Equity Workgroup - All Goals

1. Generate and disseminate real-world evidence about the substantial public health issue of health inequities

2. 3 fully-reproducible study packages executed across at least 20 OHDSI data partners

3. 10 publications accepted in peer-reviewed journals

4. 10 instances of presentations of our work

5. 10 uses of OHDSI results by internal or external stakeholders that demonstrate influence in policy or clinical decision-making

### Standards for studying patient-level Social Determinants of Health, Risk factors, and Needs (SDRN)

1. Identify 5 priority use cases for patient-level SDRN, providing recommendations for storing, collecting, and mapping the relevant common data elements

2. Provide a recommendation (to data collectors like health systems) for screening tools useful for Health Equity research

3. Identify 3 standard concepts for the data collected in recommended and commonly used screening tools

4. Engage with NLP team to release tools/methods for extracting SDRN from notes

5. Validate NLP tool for extracting 5DoH in the context of a study

### Standards for studying community-level SDRN

1. Identify 3 external datasets useful for incorporation in health equity studies

2. Identify a priority use case for linking place-based 5DoH datasets to OMOP data

3. Identify a priority use case for rolling up patient-level OMOP data to describe spatial-population-level properties

4. Release a study package using GIS tools to gain a better understanding of health inequities

### Extend OHDSI tools to make a health equity perspective the default and/or an option

1. Augment Patient Level Prediction (PLP) to expose the differences of predictions, predictive power, and other fairness metrics of the predictive models it creates

2. Release tools to assess data quality / gaps for 5DoH

3. Develop a framework for best practices in health equity across study design

### Engage the broader community on issues related to health equity

1. Release directories of accessible educational resources and research relevant to health equity

2. Engage early-stage researchers group for researcher diversity and inclusion in our work

3. Engage education workgroup for health equity educational content

4. Organize health equity reading group / journal club

### Support the work of the group

1. Apply, as a group, for a grant

Thanks Jake Gillberg!
HADES workgroup

Enable the OHDSI community to perform observational research following OHDSI best practices for characterization, population-level estimation, and patient-level prediction by providing a cohesive set of open-source analytic software

• To reduce dependency on a small number of developers, reduce the maximum number of packages per maintainer to 5 (5)
• Increase the unit test coverage to > 80% for all packages, require 2 QA to review test cases (10)
• Release 4 study package skeletons, and make sure they are directly available to users (3)

Thanks Martijn Schuemie!
OHDSI Vaccine Vocabulary Workgroup
2021 OKR Review

Objective:
A clear and complete standard vaccine hierarchy and accurate vaccine mappings in the OMOP Vocabulary

Key results:
- Define use cases and problems with current standard vaccine vocabulary
- Develop a solution and solicit feedback from the OHDSI community
- Implement the solution (new vocabulary, new relationships, improved mappings)
1. **Objective**: Build a casual environment for younger community members to collaborate.

   **Key Result**:  
   - Monthly bi-hemisphere meetings to accommodate for younger community members in various time zones - 9  
     - Scoring this as 9 because we’ve definitely generated a casual environment for junior researchers through meetings and through a group chat to feel comfortable bouncing ideas and asking questions. However, it’s not a 10 because I think we can find a better time for both hemispheres to increase attendance.

2. **Objective**: Encourage junior researchers to gain experience in running OHDSI projects.

   **Key Result**:  
   - Draft our own study protocol - 1  
     - Scoring this as 1 because we didn’t quite make any progress on it. We have discussed research that various members are doing, but have not proposed or come to a consensus on potential study topics.

3. **Objective**: Invite community members to discuss and present research

   **Key Result**:  
   - Organize demos on how to use all the tools in OHDSI (e.g. HADES packages, Atlas, etc.)  
   - Invite researchers to present on various topics (e.g. standard ETL process) - 7  
     - Scoring this as 7 because we’ve had 2 scheduled tutorials (Patient Level Prediction & Cohort Building) by request.

4. **Objective**: Provide educational resources and a space to learn interactively and collaboratively

   **Key Result**:  
   - Work with Roux Institute to advance OHDSI education (e.g. create a condensed version of the Book of OHDSI for beginners)  
   - Create a centralized repository to store code that newcomers can use when they are just getting started - 2  
     - Scoring this a 2 because we’ve made progress by meeting with individuals at the Roux Institute (Kristin Kostka and Brianne Mui) to brainstorm several ways of advancing OHDSI education, but we have not executed those ideas yet. We need to have follow up meetings with Roux.
Lots more community enablement

- **OHDSI2021 Symposium**
  - 1368 registered, 500-700 attending each session

- **OHDSI weekly community calls**
  - ~150-200 collaborators/week

- **OHDSI communication channels**
  - MSTeams: 2,774 registered users in OHDSI team
  - LinkedIn: 2,815 followers, 5-20k impressions/month
  - Twitter: 2,251 followers,
  - YouTube: 80 hrs created, 7,260 hrs watched
Which community meeting format did you prefer?

- Network Sessions in Teams
- Network Sessions in GatherTown
- Workgroup Updates
- Multiple Presentations Under Single Topic
- Welcome To The Journey (for newcomers)
- Focus Sessions (FDA Best/EHDEN/EUMAES/ etc)
- 10-Minute Tutorials
- Open Studies
- OHDSI Fun
- OKR Start, Mid-Year, Final Review
- Visualization Challenge
- Debates
- Meet-And-Greet
- Back To School
- Meet The Titans
- History of OHDSI
- Community Brainstorm (Health Equity)
Engine of Impact
(Dec Status)

Education
- Youtube
- Ehden

Engagement
- Github
- MS Teams

Impact
- Pubmed

On deck
In Progress
Done

Thanks Paul Nagy!
### Youtube Data API (Public)  
**OHDSI Channel as of 2014 to 2021-12-01**

<table>
<thead>
<tr>
<th>Stat</th>
<th>Stats</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of videos submitted on OHDSI channel</td>
<td>450</td>
</tr>
<tr>
<td>Total number of hours created (2014-)</td>
<td>304</td>
</tr>
<tr>
<td>Total number of person years viewed (2000 hr/yr)</td>
<td>80.11</td>
</tr>
<tr>
<td>2021 number of videos</td>
<td>169</td>
</tr>
<tr>
<td>2021 videos hours created</td>
<td>78</td>
</tr>
<tr>
<td>2021 videos hours viewed</td>
<td>7,260</td>
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</table>
Additional resources about OKRs

• Google page: https://rework.withgoogle.com/guides/set-goals-with-okrs/steps/set-objectives-and-develop-key-results/

• Measure What Matters, John Doerr: https://www.whatmatters.com/