

Where have we been?
Where are we going?
OHDSI OKR mid-year review

Patrick Ryan, PhD

Janssen Research & Development

Columbia University



OHDSI's mission



Where have we been Where should we go in 2021?

Patrick Ryan PhD anssen Research & Developmen

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



12 Jan 2021



Where have we been?
Where should we go in 2021?

Patrick Ryan, PhD Janssen Research & Development Columbia University

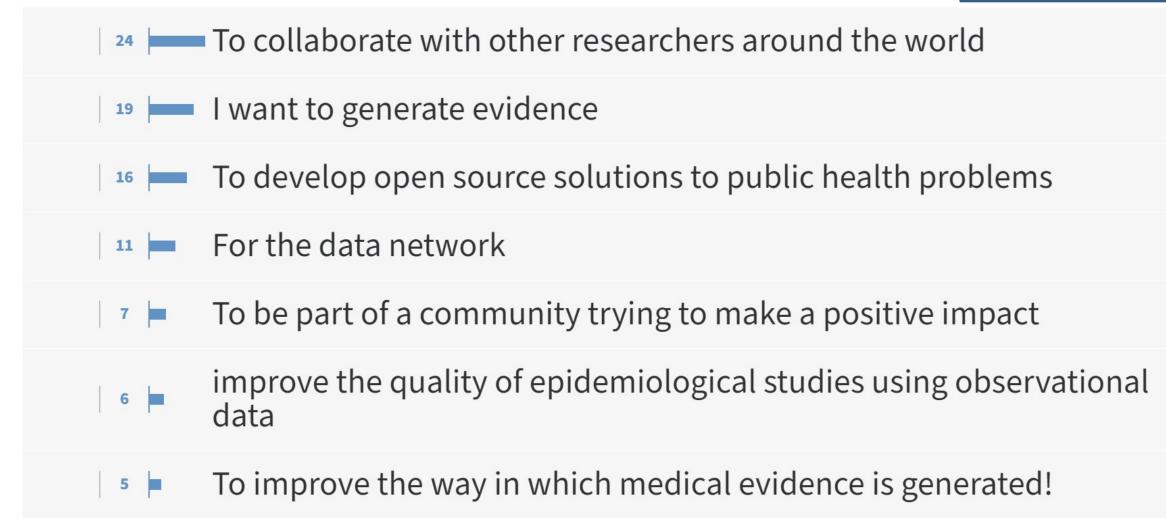




Why are you on the journey with OHDSI?

12 Jan 2021 **OHDS**

Top





An organizing framework



Where have we been?
Where should we go in 2021?

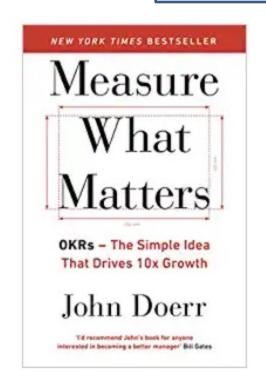
12 Jan 2021

Patrick Ryan, PhD

Janssen Research & Development

Columbia University

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





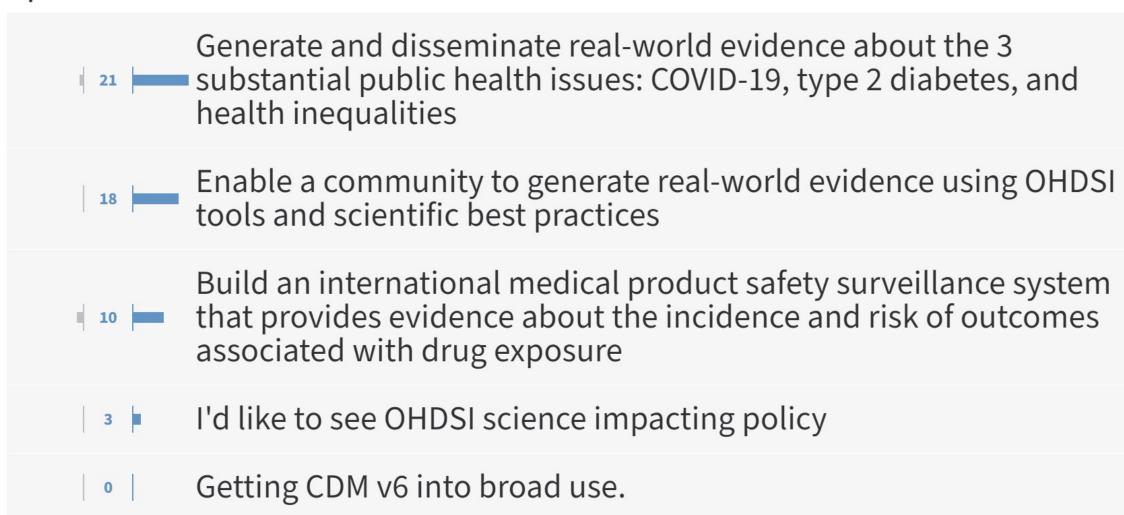
Writing effective OKRs



- 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.

What should be OHDSI's 2021 Objectives?

Top





OKR review and grading

Score range	Question to ask:
9.5 - 10	Are we being ambitious enough?
6.5 - 9.4	What have we learned?
4.0 - 6.4	How can we focus/help?
1.5 - 3.9	What do we need to change?
0 - 1.4	Should this remain an priority objective?



What are your reflections on OHDSI's progress towards its 2021 objectives and key results (OKRs)?

Top

- We should continue with our objective, "Build an international medical product safety surveillance system that provides all stakeholders access to evidence abo...
- We should continue with our objective, "Enable a community to generate real-world evidence using OHDSI tools and scientific best practices"
- We should continue with our objective, "Generate and disseminate real-world evidence about the 3 substantial public health issues: COVID-19, type 2 diabetes,...



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



README.md

Evaluating Use of Methods for Adverse Event Under

Surveillance (for vaccines)

Study Status Results Available

- Analytics use case(s): Population-Level Estimation
- Study type: Methods Research
- Tags: -
- Study lead: Martijn Schuemie
- Study lead forums tag: schuemie
- Study start date: January 12, 2021
- Study end date: -
- Protocol: HTML document, ENCEPP registration
- · Publications: -
- Results explorer: Shiny app

Similar to our previous research on the evaluation of causal effe systematically evaluate methods for (safety) surveillance of vacc Calculating the background rates of adverse events of special interest (AESI) for the COVID vaccines

0

Study Status Design Finalized

:≡ README.md

- Analytics use case(s): Characterization
- Study type: Clinical Application
- Tags: COVID-19
- Study lead: George Hripcsak, Patrick Ryan, Marc Sucha
- Study lead forums tag: Patrick_Ryan
- Study start date: -
- Study end date: -
- Protocol: pdf file
- Publications: -
- · Results explorer: -

Calculating the background rates of adverse events of spe

Evaluating the Sensitivity Of Prediction Model Development and Performance Due To Phenotypes Applied To COVID-19 VACCINES

0

Study Status Started

- Analytics use case(s): Patient-Level Prediction
- Study type: Methods Research, Clinical Application
- Tags: COVID-19
- Study lead: Jenna Reps
- Study lead forums tag: jreps
- Study start date: 2021-03-21
- Study end date: -
- · Protocol: Click Here
- · Publications: -
- Results explorer: -

Method research into the target population and outcome phenotypes we should use to develop COVID-19 vaccine prediction models for various outcomes of interest

Key result 2: 10 publications accepted in journals with impact factor > 10

PEDIATI RHEUMATOLOGY

Rheumatology 2021;0:1–14 doi:10.1093/rheumatology/keab250

RESEARCH









Use of repurposed and adjuvant drugs in hospital patients with covid-19: multinational network cohort study

Albert Prats-Uribe, ¹ Anthony G Sena, ^{2,3} Lana Yin Hui Lai, ⁴ Waheed-Ul-Rahman Ahmed, ^{5,6} Heba Alghoul, ⁷ Osaid Alser, ⁸ Thamir M Alshammari, ⁹ Carlos Areia, ¹⁰ William Carter, ¹¹ Paula Casajust, ¹² Dalia Dawoud, ^{13,14} Asieh Golozar, ^{15,16} Jitendra Jonnagaddala, ¹⁷ Paras P Mehta, ¹⁸ Mengchun Gong, ¹⁹ Daniel R Morales, ^{20,21} Fredrik Nyberg, ²² Jose D Posada, ²³ Martina Recalde, ^{24,25} Elena Roel, ^{24,25} Karishma Shah, ⁵ Nigam H Shah, ²³ Lisa M Schilling, ¹¹ Vignesh Subbian, ²⁶ David Vizcaya, ²⁷ Lin Zhang, ^{28,29} Ying Zhang, ¹⁹ Hong Zhu, ³⁰ Li Liu, ³⁰ Jaehyeong Cho, ³¹ Kristine E Lynch, ³² Michael E Matheny, ^{33,34} Seng Chan You, ³⁵ Peter R Rijnbeek, ³ George Hripcsak, ³⁶ Jennifer CE Lane, ⁵ Edward Burn, ^{1,24} Christian Reich, ³⁷ Marc A Suchard, ³⁸ Talita Duarte-Salles, ²⁴ Kristin Kostka, ^{37,39} Patrick B Ryan, ^{2,40} Daniel Prieto-Alhambra¹

Talita | Yin Hi Algh Du Mengchi Jose I Shah, Geo

Cite

77

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DOI: 10

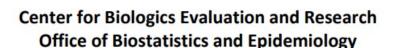




Key result 3: 10 uses of OHDSI results by external stakeholders that demonstrate influence in policy or clinical decision-making







CBER Surveillance Program

COVID-19 Vaccine Safety Surveillance: Active Monitoring Master Protocol

EUROPEAN MEDICINES AGENCY Search SCIENCE MEDICINES HEALTH Veterinary regulatory >

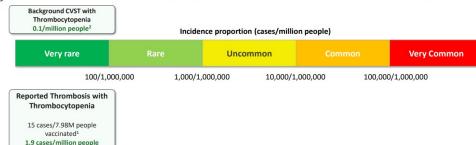
AstraZeneca's COVID-19 vaccine: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets

< Share

News 07/04/2021

EMA confirms overall benefit-risk remains

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



February 10, 2021



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.

COVID-19:

6.5

Type 2 diabetes:

3

Health inequalities:

0



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

?

9

6



EHDEN Academy Marks One-Year Anniversary with 1,000th Enrollee

26th April 2021







Journal Article

Meta-Analysis

Preprint

("OMOP" or "OHDSI") AND ("2021/01/01"[Date - Publication] : "3000"[Date -Search

Advanced Create alert Create RSS

Share

PMID: 34042878

repository....

User Guide

Display options Sorted by: Most recent ↓= Save Email Send to MY NCBI FILTERS L 34 results Evaluation of the Privacy Risks of Personal Health Identifiers and Quasi-Identifiers RESULTS BY YEAR in a Distributed Research Network: Development and Validation Study. Oh S, Sung M, Rhee Y, Hong N, Park YR. JMIR Med Inform. 2021 May 31;9(5):e24940. doi: 10.2196/24940. Share PMID: 34057426 METHODS: We detected PHIs and QIs in an Observational Medical Outcomes Partnership (OMOP) CDM as threatening privacy, based on 18 Health Insurance Portability and Accountability Act of 1996 (HIPPA) 2020 2021 identifiers and previous studies. To compare the privacy risk according to ... TEXT AVAILABILITY Accessing OMOP Common Data Model Repositories with the i2b2 Webclient -Algorithm for Automatic Query Translation. Abstract Majeed RW, Fischer P, Günther A. Free full text Stud Health Technol Inform. 2021 May 24;278:251-259. doi: 10.3233/SHTI210077. Full text PMID: 34042902 In the era of translational research, data integration and clinical data warehouses are important enabling ARTICLE ATTRIBUTE technologies for clinical researchers. The OMOP common data model is a wide-spread choice as a target for data integration in medical informatics. ... Aim of this stud ... Associated data ARTICLE TYPE HIStream-Import: A Generic ETL Framework for Processing Arbitrary Patient Data Collections or Hospital Information Systems into HL7 FHIR Bundles. **Books and Documents** Majeed RW, Stöhr MR, Günther A. Clinical Trial

Stud Health Technol Inform. 2021 May 24;278:75-79. doi: 10.3233/SHTI210053.

We evaluated an implementation of the algorithm using different lung research registries and used the

resulting FHIR resources to fill our i2b2 based data warehouse as well an OMOP common data model



OHDSI in 2021

Objective:

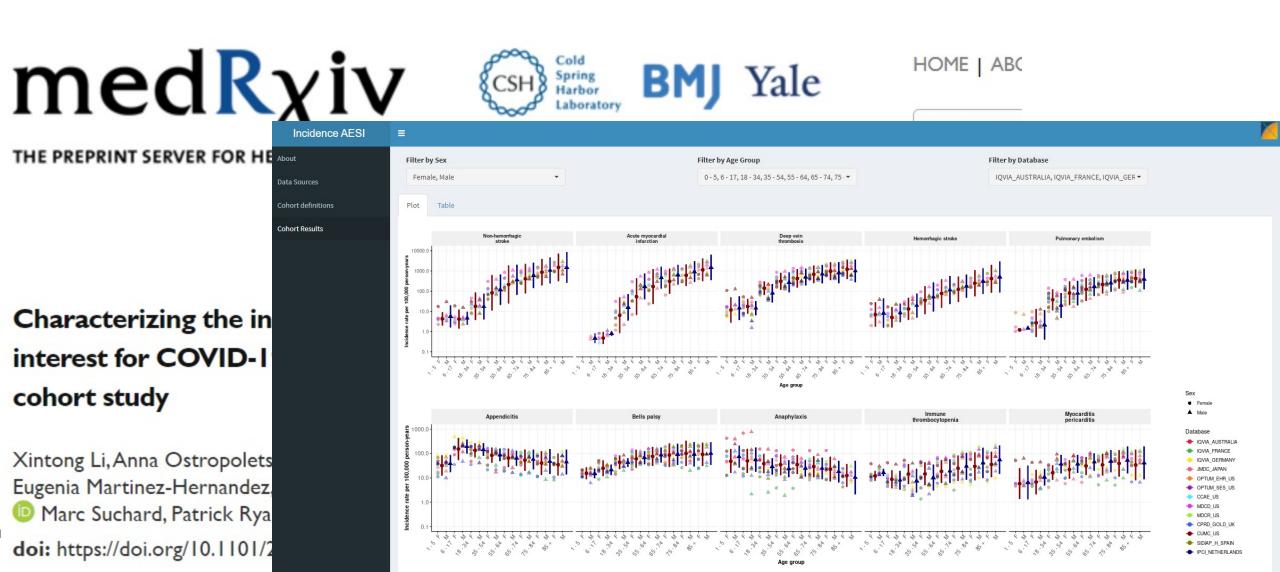
Build an international medical product safety surveillance system that provides all stakeholders access to evidence about the incidence and risk of outcomes associated with drug exposure

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



Key results: Population-level effect estimation and characterization results generated for 500 drugs and 500 outcomes across 20 databases





Pharmacovigilance and Clinical Environment: Utilizing OMOP-CDM and OHDSI Software Stack to Integrate EHR Data

Vlasios K Dimitriadis ¹, George I Gavriilidis ¹, Pantelis Natsiavas ¹

Affiliations + expand

PMID: 34042637 DOI: 10.3233/SHTI210232

However, we argue that using OMOP-CDM as a reference data model to integrate EHR data for PV purposes entails significant benefits. First, given that OMOP-CDM is a widely accepted data model, it provides a potential gateway to a big data sharing ecosystem. Furthermore, OMOP-CDM could be used to integrate other kinds of data (e.g., claims databases). Finally, the statistical and analytics tools developed by OHDSI are supported by an ecosystem of widely recognized experts, with a proven record of highly valuable results on observational studies. Although these tools are not explicitly developed for PV purposes, there is significant merit in repurposing them towards PV due their analytical prowess. This repurposing approach could be an important next step, providing significant value for both the drug safety and OHDSI ecosystem.

OHDSI MSTeams Work groups, Chapters, and Studies Registration

OHDSI is using MSTeams to further encourage active collaboration within the community. Within the OHDSI organization, there are separate teams for work groups, chapters, and studies, as well as OHDSI community activities (such as the OHDSI2020 Symposium). All teams are open to all collaborators. Below please indicate which Team you would like to join and the OHDSI coordinating center team will grant access.

5. Select the workgroups you want to join (you can refer to the WIKI for work group objectives www.ohdsi.org/web/wiki/doku.php?id=projects:overview) Medical Devices ATLAS Population-Level Effect Estimation / Patient-Level Prediction Natural Language Processing Clinical Trials Psychiatry OHDSI APAC Common Data Model Registry (formerly UK Biobank) OHDSI APAC Steering Committee Data Quality Dashboard Development Surgery and Perioperative Medicine OHDSI Steering Committee Early-stage Researchers Vaccine Safety Oncology Education Work Group Vaccine Vocabulary Patient-Generated Health Data Electronic Health Record (EHR) ETL Women of OHDSI Pharmacovigiliance Evidence Investigation Geographic Information System (GIS) Phenotype Development and Evaluation HADES Health Analytics Data-to-Evidence Suite

Latin America



Common Data Model Workgroup OKRs

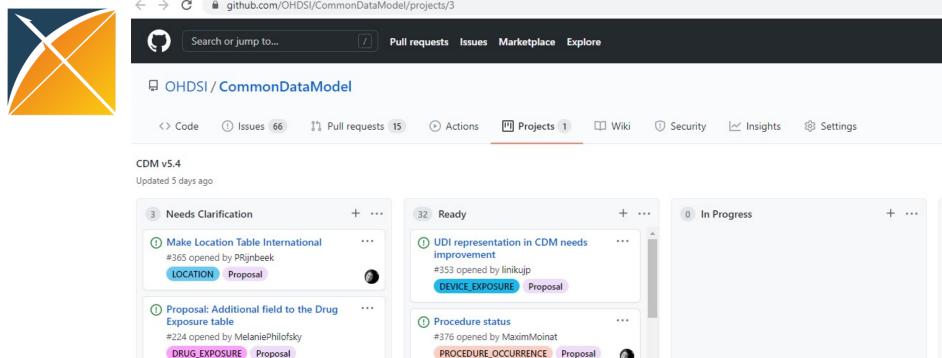
- Develop and promote community adoption of CDM v6.x
 - KR1: A list of all changes and additions to be made fully communicated to all stakeholders (Q1)
 - KR2: 100% agreement from all affected workgroups by Q2
 - KR3: Release of DDLs by Q3
- Establish clear by-laws dictating the CDM change process and versioning
 - KR1: Draft initial guidelines for use cases and use case ownership by Q1
 - KR2: Draft initial guidelines for CDM model extension and versioning by Q2
 - KR3: 100% agreement from the community on proposed guidelines by Q4

10

7.5

2

7.5

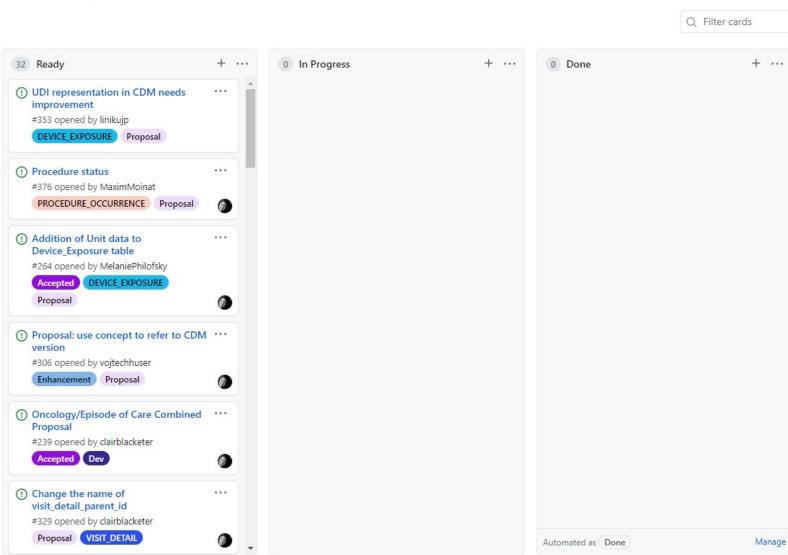


① Add PROCEDURE_END_DATETIME field

PROCEDURE_OCCURRENCE Proposal

to PROCEDURE_OCCURRENCE

#286 opened by nadavrap





Population-level Estimation / Patient-level Prediction Methods Research Agenda

- Methods for vaccine effect estimation
 - Vaccine safety surveillance overall method evaluation (EUMAEUS)
 - Effect of outcome definition operating characteristics on vaccine safety surveillance
 - Comparative vaccine effectiveness in RWD
- Phenotype research
 - Validation of methods for establishing phenotype operating characteristics (e.g. PheValuator, guided patient profile review).
- Prediction
 - Investigate the impact that target and outcome definitions have on prediction models (i.e., are the models stable or unstable to small definition changes)
 - Investigate the use of proxy targets when developing models
 - Establishing a prediction model library
- Small-databases challenges
 - Few exposed: evaluation of balance metrics when counts are low
 - Few exposed: methods for addressing confounding when counts are low (e.g. cardinality matching, dimensionality reduction before PS fitting, informed priors for our PS models)

9

3

9

5



HADES OKR

- **Objective**: 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
 - Key result 1: To reduce dependency on a small number of developers,
 reduce the maximum number of packages per maintainer to 5
 - Key result 2: Increase the unit test coverage to > 80% for all packages
 - Key result 3: Release 4 study package skeletons, and make sure they are directly available to users



KR1: Expand package ownership:

 11 different developers maintaining HADES packages

KR1: Expand package ownership:

- Martijn still owns 10 packages
- We need broader support from community to distribute workload

Package statuses

The table below lists, for each of the HADES packages, the following details:

- Version: The latest released version.
- Maintainer(s): The persons responsible for the package. Only maintainers can create releases.
- Availability: whether the package can be installed from CRAN (using install.packages()), or needs to be installed from GitHub (using remotes::install github()).
- . Open issues: The number of open issues.
- Open pull-requests: The number of open pull-requests
- Build status: Whether the package passes R Check (including unit tests) on several different operating systems, and using various database
 platforms. The status shown is of the the latest push, including those to develop branches. Released packages (in the master branch) by
 definition have successful builds, and are not shown here.
- Coverage: The percentage of lines of code that is covered by the unit tests in the master branch (i.e. in the latest released version).

Package	Version	Maintainer(s)	Availability	Open issues	pull- requests	Build status	Coverage
Andromeda	v0.4.1	Adam Black	CRAN	8	1	(R-CMD-check passing	codecov 87%
<u>BigKnn</u>	v1.0.0	Martijn Schuemie	GitHub	1	0	(R-CMD-check passing	codecov unknown
CirceR	v1.1.1	Chris Knoll	GitHub	1	0	R-CMD-check passing	Codecov 87%
CohortDiagnostics	v2.1.0	Gowtham Rao	GitHub	19	1	R-CMD-check passing	Codecov 81%
CohortMethod	v4.1.0	Martijn Schuemie	GitHub	5	0	R-CMD-check passing	
Cyclops	v3.1.1	Marc Suchard	CRAN	7	0	R-CMD-check passing	Codecov 66%
DatabaseConnector	v4.0.2	Martijn Schuemie	CRAN	16	1	R-CMD-check passing	codecov 40%
EmpiricalCalibration	v2.1.0	Martijn Schuemie	CRAN	0	0	R-CMD-check passing	Codecov 0%
Eunomia	v1.0.1	Frank DeFalco	CRAN	0	0	R-CMD-check passing	codecov 72%
<u>EvidenceSynthesis</u>	v0.2.3	Martijn Schuemie	CRAN	0	0	R-CMD-check passing	codecov 41%
FeatureExtraction	v3.1.1	Anthony Sena	GitHub	21	2	R-CMD-check passing	Codecov 16%
<u>Hydra</u>	v0.2.0	Martijn Schuemie	GitHub	9	6	R-CMD-check passing	codecov 0%
MethodEvaluation	v2.1.0	Martijn Schuemie	GitHub	3	0	R-CMD-check passing	codecov 0%
OhdsiSharing	v0.2.2	Lee Evans	GitHub	1	1	R-CMD-check passing	codecov 0%
<u>ParallelLogger</u>	v2.0.1	Martijn Schuemie	CRAN	3	0	R-CMD-check passing	codecov 55%
PatientLevelPrediction	v4.3.7	Jenna Reps & Peter Rijnbeek	GitHub	25	1	R-CMD-check passing	codecov 14%
ROhdsiWebApi	v1.2.0	Gowtham Rao	GitHub	11	1	R-CMD-check passing	Codecov 10%
<u>SelfControlledCaseSeries</u>	v3.0.0	Martijn Schuemie	GitHub	8	0	R-CMD-check passing	codecov 53%
SelfControlledCohort	v1.5.1	Jamie Gilbert	GitHub	0	0	R-CMD-check passing	codecov 95%
SqlRender	v1.7.0	Martijn Schuemie	CRAN	31	1	R-CMD-check passing	

KR2: Test coverage > 80%:

- Great job for the progress!
- Adam Black (Andromeda)
- Chris Knoll (Circe)
- Gowtham Rao (CohortDiagnostics)
- Jamie Gilbert (SelfControlledCohort)
- Martijn Schuemie (SqlRender)

KR2: Test coverage > 80%:

- 14 of 20 packages still don't meet the HADES target
- More community support in developing test cases is needed

https://ohdsi.github.io/Hades/packageStatuses.html



What are your reflections on OHDSI's progress towards its 2021 objectives and key results (OKRs)?

Top

- We should continue with our objective, "Build an international medical product safety surveillance system that provides all stakeholders access to evidence abo...
- We should continue with our objective, "Enable a community to generate real-world evidence using OHDSI tools and scientific best practices"
- We should continue with our objective, "Generate and disseminate real-world evidence about the 3 substantial public health issues: COVID-19, type 2 diabetes,...



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: <u>https://www.whatmatters.com/</u>