

Cancer OMOP, the global community and vision

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Asieh Golozar, MD PhD MHS MPH





OHDSI is a Global Success

OMOP Data by the Numbers

- 534 data sources
- 49 countries
- 956 million unique patient records
- approximately 12% of the world's population

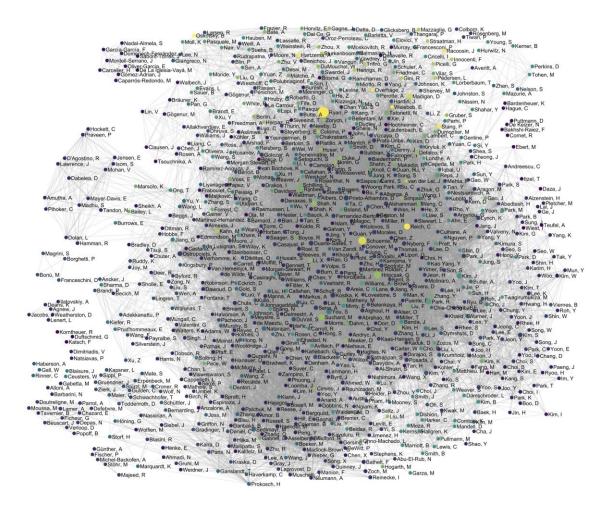
OHDSI By The Numbers

- 3,758 collaborators
- 83 countries
- 21 time zones
- 6 continents
- 1 community



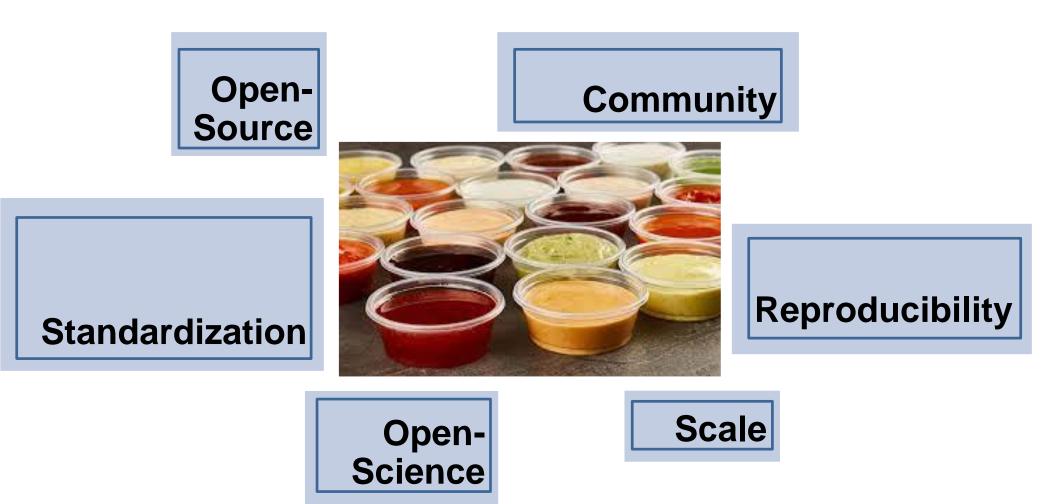
Collaborations in Scholarship

- More than 600 peer-reviewed studies relating to OMOP or OHDSI tools/methods/best practices have been published over the last decade
- Most papers have multiple authors, and OHDSI continues to see a rise in new authors collaborating on studies



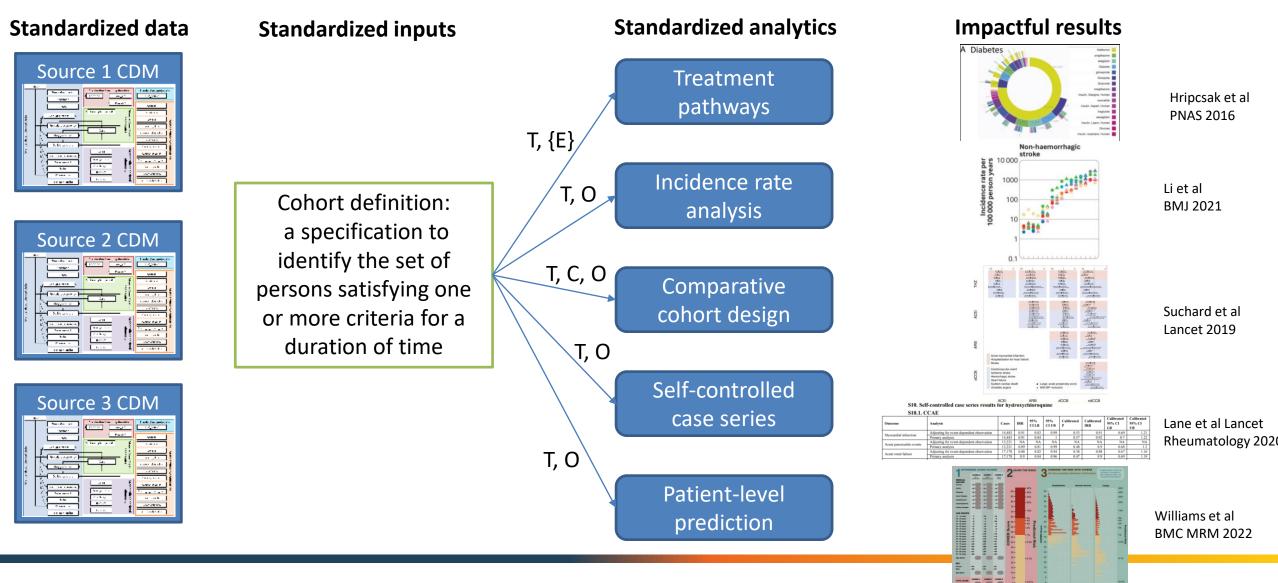


The Secret Sources



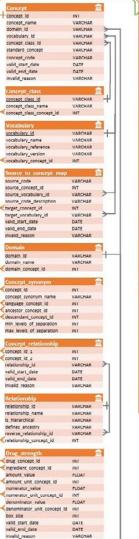


Journey to Evidence Streamlined with Standardization





Data Standardization: OMOP CDM



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paid_patient_consurance paid_patient_deductible	FLOAT	
paid_by_primary	FLOAT	
paid_ingredient_cost	FLOAT	
paid_ingredient_cost paid_dispensing_fee	FLOAT	
payer_plan_period_id	INT	2
imount_allowed	FLOAT	ſ
revenue_code_concept_id	INT	
revenue_code_source_value	VARCHAR	
drg_concept_id	INT	
drg_source_value	VARCHAR	
Payer_plan_period		
payer plan period id	INT	ŀ
person_id	INT	
payer_plan_period_start_date	DATE	
payer_plan_period_end_date	DATE	
payer_concept_id	INT	1
payer_source_value	VARCHAR	
payer_source_concept_id	INT	
plan_concept_id	INT	
plan_source_value	VARCHAR	
	INT	
plan_source_concept_id		
plan_source_concept_id sponsor_concept_id	INT	
plan_source_concept_id sponsor_concept_id sponsor_source_value	VARCHAR	
plan_source_concept_id sponsor_concept_id sponsor_source_value sponsor_source_concept_id	VARCHAR	l
plan_source_concept_id sponsor_concept_id sponsor_source_value sponsor_source_concept_id family_source_value	VARCHAR INT VARCHAR	l
plan_source_concept_id sponsor_concept_id sponsor_source_value sponsor_source_concept_id family_source_value stop_reason_concept_id	VARCHAR INT VARCHAR INT	
plan_source_concept_id sponsor_concept_id sponsor_source_value sponsor_source_concept_id family_source_value	VARCHAR INT VARCHAR	

	Contaitinging Cra		
	condition era.id	INT	
1	Verson_id	INT	
	<pre>condition_concept_id</pre>	INT	
	condition_era_start_date	DATE	
	condition_era_end_date	DATE	
	condition_occurrence_count	INT	
	Press of the second		
	Drug_era		8
1	drug era id person_id	INT	
	drug_concept_id	INT	
	drug_era_start_date	DATE	
	drug_era_end_date	DATE	
	drug_exposure_count	INT	
	gap_days	INT	
	Duxe era		
	dose era id	INT	
1	<pre>person_id</pre>	INT	
	drug_concept_id	INT	
	<pre>unit_concept_id</pre>	INT	
	dose_value	FLOAT	
	dose_era_start_date	DATE	
	dose_era_end_date	DATE	
	Episode		8
	episode id	INT	14
1	person_id	INT	Ľ
	episode_concept_id	INT	
	episode_start_date	DATE	
	episode_start_datetime	DATETIME	
	episode_end_date	DATE	
	episode_end_datetime	DATETIME	
	episode_parent_id	INT	
	episode_number	INT	
	episode_object_concept_id	INT	
	episode_type_concept_id	INT	
	episode_source_value	VARCHAR	
	episode_source_concept_id	INT	
	Episode event	2	
	episode id	INT	5
	event_id	INT	1
	episode event field concept id	INT	
	Cohort	()	
	cohort_definition_id	INT	7
	subject_id	INT	
	cohort_start_date	DATE	
	cohort_end_date	DATE	
	Cohort_definition	5	
	cohort_definition_id	INT	14
	cohort_definition_name	VARCHAR	11
	cohort_definition_description	VARCHAR	
	definition_type_concept_id	INT	
	cohort_definition_syntax	VARCHAR	
1	subject_concept_id	INT	
	cohort initiation date	DATE	

Condition era





Open-Source Community

- 262 Repositories
- 30 M+ lines of code
- 681 Developers
- 31 organizations
- 47,672 commits
- 2,838 GitHub Forks
- 4,168 GitHub Stars
- 5,547 GitHub Subscribers

IHADES 🏫 🗊 Package	s 🗳V	alidation 🛛 🌮 Publ	ications 🧕	Support •		dy packages 👻	🔑 Developer:
Package	Version	Maintainer(s)	Availability	Open issues	pull- requests	Build status	Coverage
Achilles	v1.7.2	Frank DeFalco	CRAN	29	3	C R check passing	Codecov 2%
Andromeda	v0.6.3	Adam Black	CRAN	13	2	C R check passing	Codecov 89%
BigKnn	v1.0.2	Martijn Schuemie	GitHub	0	0	C R check passing	Codecov 96%
<u>BrokenAdaptiveRidge</u>	v1.0.0	Marc Suchard	CRAN	2	0	C R check passing	Codecov 969
<u>Capr</u>	v2.0.7	Martin Lavallee	GitHub	2	0	C R check passing	Codecov 809
<u>Characterization</u>	v0.1.2	Jenna Reps	GitHub	11	1	C R check failing	Codecov unknow
CirceR	v1.3.1	Chris Knoll	GitHub	3	1	C R check passing	Codecov 899
<u>CohortDiagnostics</u>	v3.2.4	Jamie Gilbert	GitHub	56	2	C R check passing	Codecov 90%
<u>CohortExplorer</u>	v0.1.0	Gowtham Rao	CRAN	0	0	C R check passing	Codecov 100%
<u>CohortGenerator</u>	v0.8.1	Anthony Sena	GitHub	19	2	C R check passing	Codecov 989
<u>CohortMethod</u>	v5.1.0	Martijn Schuemie	GitHub	14	1	C R check failing	Codecov 889
<u>Cyclops</u>	v3.3.1	Marc Suchard	CRAN	18	0	C R check failing	Codecov 859
DatabaseConnector	v6.2.4	Martijn Schuemie	CRAN	12	0	C R check passing	Codecov 599
<u>DataQualityDashboard</u>	v2.4.1	Katy Sadowksi	GitHub	43	7	C R check passing	Codecov 869
DeepPatientLevelPrediction	v2.0.0	Egill Fridgeirsson	GitHub	18	1	R check failing	Codecov 100%
EmpiricalCalibration	v3.1.1	Martijn Schuemie	CRAN	1	0	C R check passing	Codecov 84%
EnsemblePatientLevelPrediction	v1.0.2	Jenna Reps	GitHub	5	0	C R check passing	Codecov unknow
Eunomia	v1.0.2	Frank DeFalco	GitHub	10	1	C R check passing	Codecov 72%
<u>EvidenceSynthesis</u>	v0.5.0	Martijn Schuemie	CRAN	3	0	C R check passing	Codecov 789
FeatureExtraction	v3.3.1	Anthony Sena	GitHub	44	6	R check failing	Codecov 939
<u>Hydra</u>	v0.4.0	Anthony Sena	GitHub	6	7	C R check failing	Codecov 879
IterativeHardThresholding	v1.0.2	Marc Suchard	CRAN	1	0	C R check passing	Codecov 929
MethodEvaluation	v2.3.0	Martijn Schuemie	GitHub	1	0	C R check passing	Codecov 59%
OhdsiSharing	v0.2.2	Lee Evans	GitHub	0	1	C R check passing	Codecov 0%
<u>OhdsiShinyModules</u>	v2.0.0	Jenna Reps	GitHub	108	2	R check failing	Codecov 799
ParallelLogger	v3.3.0	Martijn Schuemie	CRAN	4	0	C R check passing	Codecov 81%
PatientLevelPrediction	v6.3.6	Jenna Reps & Peter Rijnbeek	GitHub	47	0	R check failing	Codecov 899
PhenotypeLibrary	v3.30.1	Gowtham Rao	GitHub	1	0	C R check passing	Codecov 1009



and are listed below

1. LEGEND will generate evidence at a

large scale. Instead of answering a single question

at a time (eq. the effect of 1 treatment on 1 outcome).

LEGEND answers large sets of related questions at once (eg, the effects of many treatments for a disease

on many outcomes). Aim: Avoids publication bias,

achieves comprehensiveness of results, and allows for

an evaluation of the overall coherence and consistency

2. Dissemination of the evidence will not

of the generated evidence

OHDSI Methods and Research

Three ideas

2. Objective Diagnostics

Engineering open science systems that build trust into the real-world evidence generation and dissemination process

Distributed data network, standardized to common data model Analysis specification Network coordinatio Data quality evaluation Phenotype development and evaluation Fail Analysis reliability evaluation Fail

3. Standardized software



Open-source software



Principles of Large-scale Evidence Generation and Evaluation across a Network of Databases (LEGEND) Martijn J. Schuemie ()^{1,2}, Patrick B. Ryan^{1,3}, Nicole Pratt⁴, RuiJun Chen ()^{3,5}, Seng Chan You⁶, Harlan M. Krumholz⁷, David Madigan⁸, George Hripcsak^{2,9}, and Marc A. Suchard^{2,1} depend on the estimated effects. All generated evidence is disseminated at once. Alm: Avoids publication bias and enhances transparence

METHODS RESEARCH

ion, 27(8), 2020, 1331-1337 loi: 10.1093/jamia/ocaa103

3. LEGEND will generate evidence using a prespecified analysis design. All analyses, including the research questions that will be answered, will be decided prior to analysis execution. Aim: Avoids P hacking.

1. LEGEND Principles

LEGEND in Principle

LEGEND (Large-scale Evidence Generation and Evaluation across a Network of Databases) applies high-level analytics to perform observational research on hundreds

of millions of patient records within OHDSI's international database network. LEGEND is based on 10 guiding principles that were published in JAMIA (August, 2020)

Perspective

4. LEGEND will generate evidence by consistently applying a systematic process across all research questions. This principle precludes modification of analyses to obtain a desired answer to any specific question. This does not imply a simple one-size-fits-all process, rather that the logic for modifying an analysis for specific research questions should be explicated and applied systematically. Aim: Avoids P hacking and allows for the evaluation of the operating characteristics of this process (Principle 6)

5. LEGEND will generate evidence using best practices, LEGEND answers each question using current best practices, including advanced methods to address confounding, such as propensity scores. Specifically, we will not employ suboptimal methods (in terms of bias) to achieve better computational efficiency. Aim: Minimizes bias

6. LEGEND will include empirical evaluation through the use of control questions. Every LEGEND study includes control questions. Control questions are questions where the answer is known. These allow for measuring the operating characteristics of our systematic process including residual bias. We subsequently account for this observed residual bias in our P values, effect estimates, and confidence intervals using empirical calibration. [7.8] Aim: Enhances transparency on the uncertainty due to residual bias

7. LEGEND will generate evidence using open-source software that is freely available to all. The analysis software is open to review and evaluation, and is available for replicating analyses down to the smallest detail. Alm: Enhances transparency and allows replication

8. LEGEND will not be used to evaluate new methods. Even though the same infrastructure used in LEGEND may also be used to evaluate new causal inference methods, generating clinical evidence should not be performed at the same time as method evaluation. This is a corollary of Principle 5, since a new method that still requires evaluation cannot already be best practice. Also, generating evidence with unproven methods can hamper the interpretability of the clinical results. Note that LEGEND does evaluate how well the methods it uses perform in the specific context of the questions and data used in a LEGEND study (Principle 6). Alm: Avoids bias and improves interpretability.

9. LEGEND will generate evidence across a network of multiple databases. Multiple heterogeneous databases (different data capture processes, health-care systems, and populations) will be used to generate the evidence to allow an assessment of the replicability of findings across sites. Alm: Enhances generalizability and uncovers potential between-site heterogeneity

10. LEGEND will maintain data confidentiality; patient-level data will not be shared between sites in the network Not sharing data will ensure patient privacy, and comply with local data governance rules, Aim: Privacy,

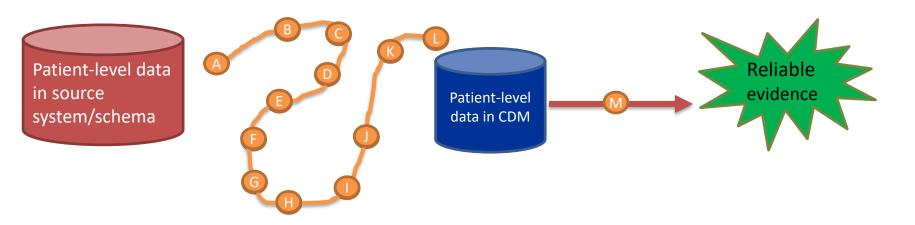
#JoinTheJourney 47 OHDSI.org System characteristics: • Standardized procedures with defined inputs and outputs Fail Analysis packages implementing scientific best practices

consistently applied across all data partners, generating consistent output for network synthesis

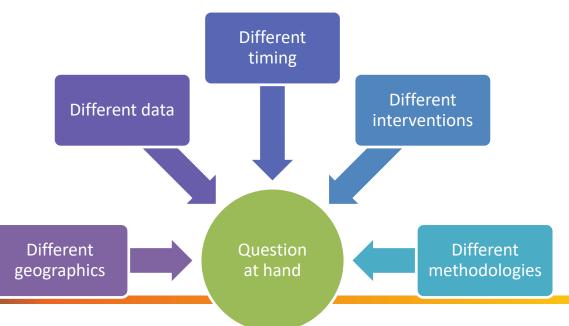
- Reproducible outputs generated by open-source analysis libraries developed and validated with verifiable unit-test coverage
- Pre-specified and objective decision thresholds for go/no go criteria
- Measurable operating characteristics of system performance



Reproducibility and Trust



A Common Data Model enables standardized analytics to generate reliable evidence.





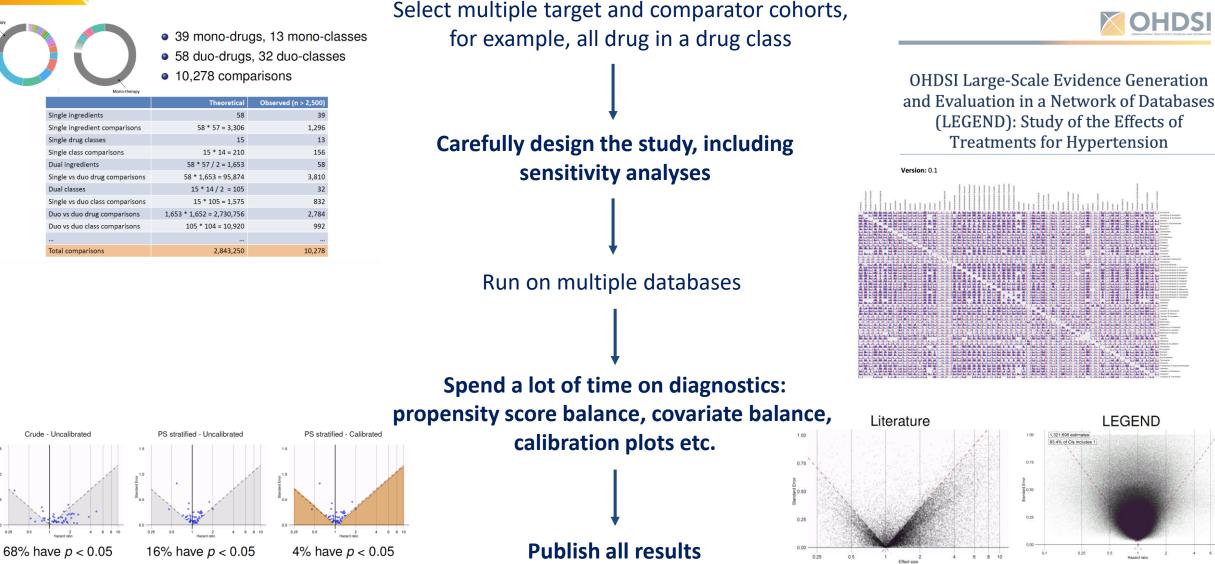
Towards Reliable Evidence ...

Some current practices across the broader research community

	Not using appropriate methods to control for bias	Modify the design until significant results are found			
	neration across a network	of databases (LEGEND)			
* Pre-specified fixed design and dissem the results regardless of the estimate publication bias)	•	: looking at thousands of target-			
* Systematic process across all research		practices: LSPS, extensive diagnostics, d positive controls			



Some of the LEGEND Principles Step-by-Step





LEGEND in practice

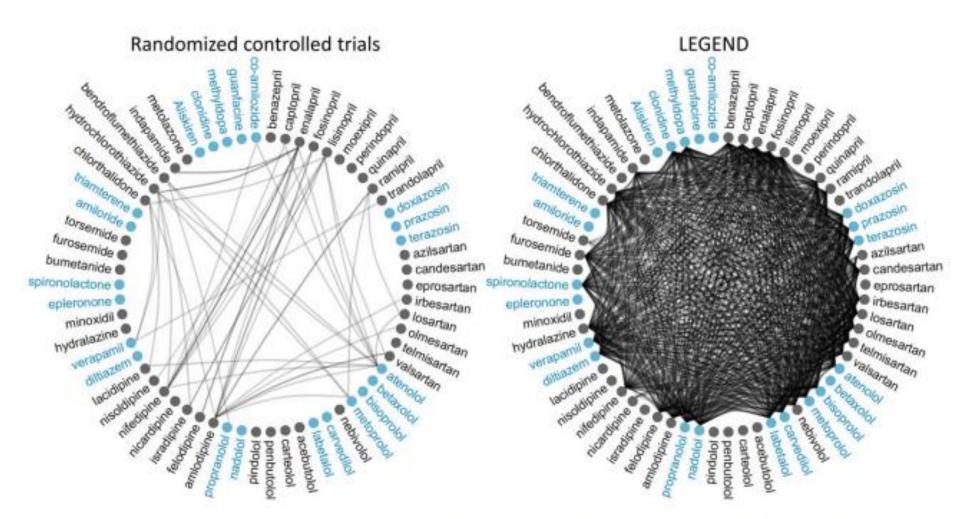


Figure 3. Comparisons of single-drug hypertension treatments in randomized controlled trials (left) and in LEGEND (right). Each circle represents an ingredient. Color groupings indicate drug classes. A line between circles indicates the 2 drugs are compared in at least 1 study.



OHDSI Scales

	Theoretical	Observed (n>2,500)
Single ingredients	58	39
Single ingredient comparisons	58 * 57 = 3,306	1,296
Single drug classes	15	13
Single class comparisons	15 * 14 = 210	156
Dual ingredients	58 * 57 / 2 = 1,653	58
Single vs duo drug comparisons	58 * 1,653 = 95,874	3,810
Dual classes	15 * 14 / 2 = 105	32
Single vs duo class comparisons	15 * 105 = 1,575	832
Duo vs duo drug comparisons	1,653 * 1,652 = 2,730,756	2,784
Duo vs duo class comparisons	105 * 104 = 10,920	992
Total comparisons	2,843,250	10,278
Outcomes of interest	58	58
Target-comparator-outcomes	2,843,250 * 58 = 164,908,500	587,020
Negative control outcomes	76	76
Target-comparator-neg controls	2,843,250 * 76=216,087,000	769,476
Positive control outcomes	76* 3=228	228
Target-comparator-pos controls	2,843,250 * 228=648,261,00	662,484
Total comparisons	864,348,000	1,431,960
Total	864,348,000 * 9= 7,779,132,000	1,431,960 * 9=12,887,640



- US Insurance databases
- IBM[®] MarketScan[®] CCAE
- IBM[®] MarketScan[®] MDCD
- IBM[®] MarketScan[®] MDCR
- Optum© Clinformatics[®]
- Japanese insurance databases
- Japan Medical Data Center
- Korean national insurance databases
- NHIS-NSC
- US EHR databases
- Columbia University Medical Center
- Optum© PANTHER[®]
- German EHR databases
- QuintilesIMS Disease Analyzer (DA) Germany



Why is oncology any different than the rest of medicine?



Problem 1: Cancer is a rare disease

HIGHLIGHTS OF PRESCRIBING INFORMATION These highlights do not include all the information needed to use TABRECTA safely and effectively. See full prescribing information for TABRECTA.

TABRECTATM (capmatinib) tablets, for oral use Initial U.S. Approval: 2020

TABRECTA is a kinase inhibitor indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). (1)

-----DOSAGE AND ADMINISTRATION------

• Select patients for treatment with TABRECTA based on presence of a mutation that leads to MET exon 14 skipping. (2.1)

• <u>Recommended dosage</u> 400 mg orally twice daily with or without food. (2.2)

-----DOSAGE FORMS AND STRENGTHS------Tablets: 150 mg and 200 mg (3)

-CONTRAINDICATIONS-

None. (4)

-----WARNINGS AND PRECAUTIONS------

- Interstitial Lung Disease (ILD)/Pneumonitis: Monitor for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Permanently discontinue TABRECTA in patients with ILD/pneumonitis. (2.3, 5.1)
- <u>Hepatotoxicity</u>: Monitor liver function tests. Withhold, dose reduce, or permanently discontinue TABRECTA based on severity. (2,3, 5.2)
 <u>Risk of Photosensitivity</u>: May cause photosensitivity reactions. Advise patients to limit direct ultraviolet exposure. (5.3)
- <u>Embryo-Fetal Toxicity. Can cause fetal harm.</u> Advise patients of the potential risk to a fetus and to use effective construction. (5.4, 8.1, 8.3)

-----ADVERSE REACTIONS-----

The most common adverse reactions ($\geq 20\%$) are peripheral edema, nausea, fatigue, vomiting, dyspnea, and decreased appetite. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Novartis Pharmaceuticals Corporation at 1-888-669-6682 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Strong and Moderate CYP3A Inducers: Avvi

------USE IN SPECIFIC PC P Lactation: Advise not to breastfeed. (8.2)

See 17 for PATIENT COUNSELING IN F approved patient labeling. HIGHLIGHTS OF PRESCRIBING INFORMATION These highlights do not include all the information needed to use TABRECTA safely and effectively. See full prescribing information for TABRECTA.

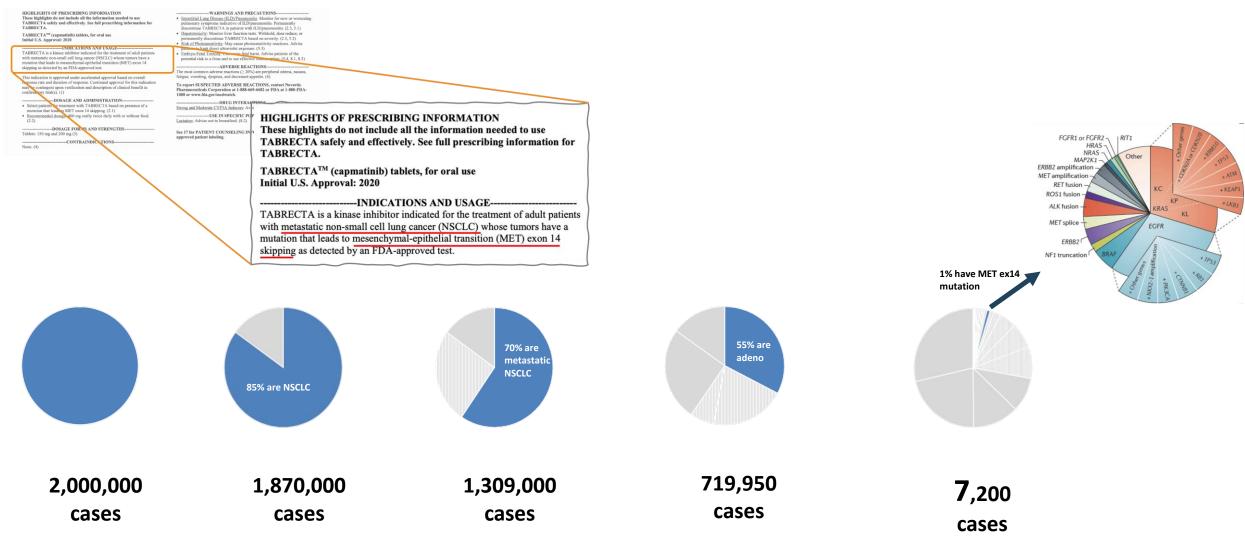
TABRECTA[™] (capmatinib) tablets, for oral use Initial U.S. Approval: 2020

-----INDICATIONS AND USAGE--

TABRECTA is a kinase inhibitor indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.



Problem 1: Cancer is a rare disease





"What is the Overall Survival or Progression-free Survival of patients with metastatic Non-small Cell Lung Cancer with confirmed MET exon 14 skipping who received oral capmatinib as first line?"



"What is the Overall Survival or Progression-free Survival of patients with metastatic <u>Non-small Cell</u> Lung Cancer with confirmed MET exon 14 skipping who received oral capmatinib as first line?"

Concept	Category
Non-small Cell	Histology



"What is the Overall Survival or Progression-free Survival of patients with metastatic <u>Non-small Cell</u> <u>Lung</u> Cancer with confirmed MET exon 14 skipping who received oral capmatinib as first line?"

Concept	Category
Non-small Cell	Histology
Lung	Anatomical site



"What is the Overall Survival or Progression-free Survival of patients with metastatic Non-small Cell Lung Cancer with confirmed MET exon 14 skipping who received oral capmatinib as first line?"

Concept	Category
Non-small Cell	Histology
Lung	Anatomical site
Metastatic disease	Tumor attribute



"What is the Overall Survival or Progression-free Survival of patients with metastatic Non-small Cell Lung Cancer with confirmed <u>MET exon 14</u> skipping who received oral capmatinib as first line?"

Concept	Category					
Non-small Cell	Histology					
Lung	Anatomical site					
Metastatic disease	Tumor attribute					
MET exon 14 skipping	Genomic Variant					



"What is the Overall Survival or Progression-free Survival of patients with metastatic Non-small Cell Lung Cancer with confirmed <u>MET exon 14</u> skipping who received oral capmatinib as <u>first line</u>?"

Concept	Category					
Non-small Cell	Histology					
Lung	Anatomical site					
Metastatic disease	Tumor attribute					
MET exon 14 skipping	Genomic Variant					
First line treatment	Treatment Episode					



"What is the Overall Survival or Progression-free Survival of patients with metastatic Non-small Cell Lung Cancer with confirmed <u>MET exon 14</u> skipping who received oral capmatinib as first line?"

Concept	Category					
Non-small Cell	Histology					
Lung	Anatomical site					
Metastatic disease	Tumor attribute					
MET exon 14 skipping	Genomic Variant					
First line treatment	Treatment Episode					
Capmatinib	Regimen					



Problem 3: No standards

There are no common or even good terminologies

Concept	Category	
Non-small Cell	Histology	ICDO, SNOMED
Lung	Anatomical site	ICDO, SNOMED
Metastatic disease	Tumor attribute	
MET exon 14 skipping	Genomic Variant	CiVIC, OncoKB, ClinVar, NCIt, CAP, LOINC, SNOMED
First line treatment	Treatment Episode	
Capmatinib	Regimen	RxNorm, HemOnc



Problem 3: No standards

Vocabularies are badly curated

- Lymph Node Status:
 - Lymph Node Status
 - Nodal Status: Para-Aortic, Mediastinal, Pelvic, Femoral Inguinal and Distant (Mediastinal, Scalene)
 - LN Status: Femoral-Inguinal, Para-Aortic, Pelvic
 - Clinical Status of Lymph Node Mets
 - Clinical Status of Lymph Nodes
- Lymph node size:
 - LN Size
 - Size of Lymph Nodes

- Mets at DX-Distant LN
- LN Distant: Mediastinal, Scalene
- Adenopathy
- Nodal Stations Involved
- Laterality
 - Laterality
 - LN Laterality
 - Regional Lymph Node Laterality



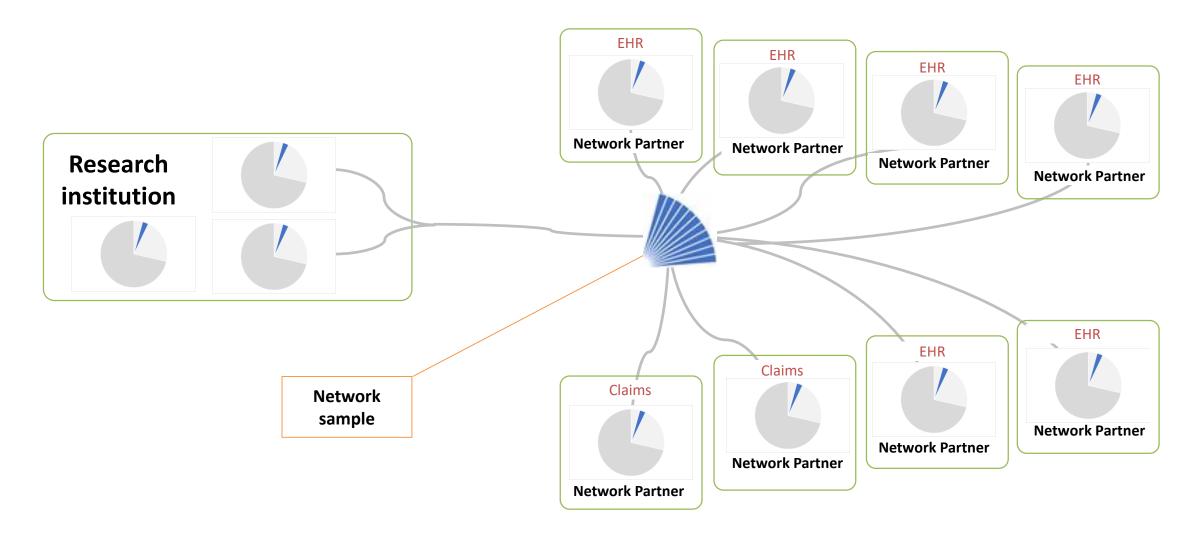
The OHDSI Oncology Working Group Has Worked on the Solution

- Oncology Network
- Oncology Module for the OMOP CDM
- Example studies



OHDSI Oncology Network

Data from many institutions can be analyzed together





OMOP CDM: Oncology Module

Solves all problems of oncology research

Cancer Disease Model

Cancer Diagnosis: Base Diagnosis + Diagnostic Modifiers (One-to-many connection between them)



Cancer Treatment Model

Composite Level (Treatment Episodes) or Individual Level (standard OMOP)



Cancer Episode Model

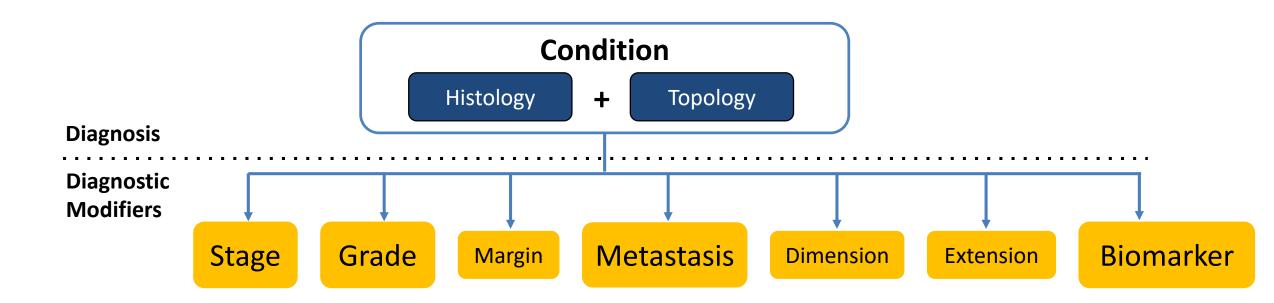
Continuous periods of disease or treatment with distinct clinical meaning Composed of multiple events

Essential for conducting cancer research



Cancer Disease Model

Cancer Diagnosis: Base Diagnosis + Diagnostic Modifiers





Abstracted chemotherapy regimens rarely available

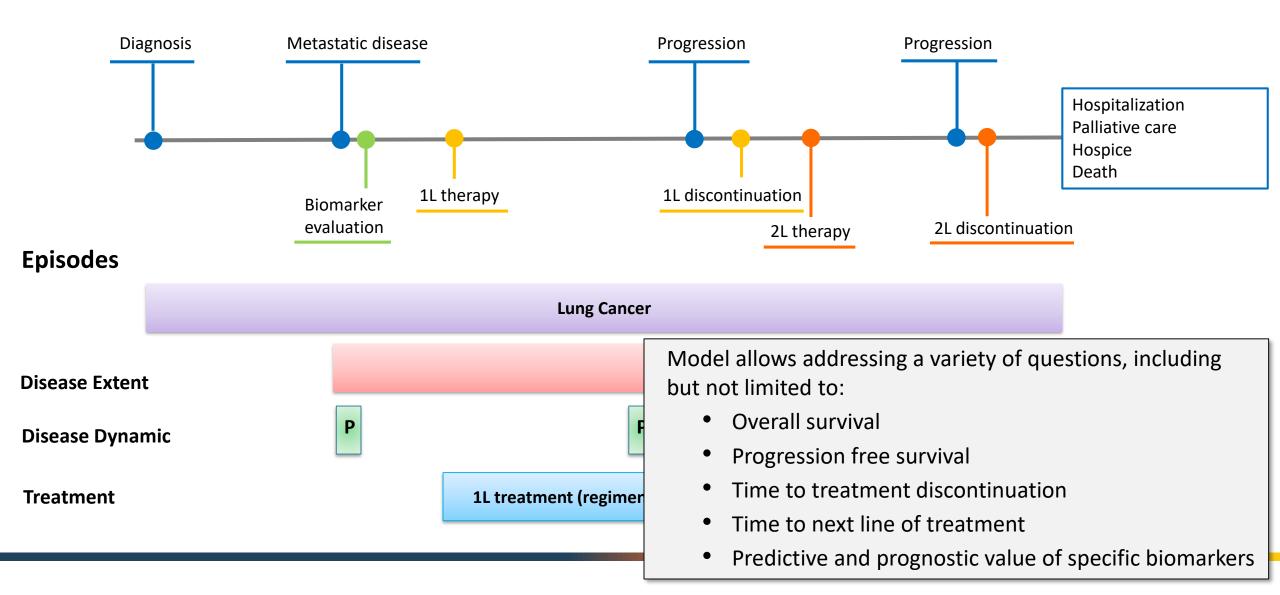
Metastatic non-Cisplatin+Gemcitabine (GC)+Bevacizumab squamous NSCLC 21-day cycle for up to 6 cycles С С С С С С GG GG GG GG GG GG Available in the data В В В В В В **Regimen 1** Needed for research but mostly not available Cycle 1 Cycle 2 Cycle 3 Cycle 4 Cycle 5 Cycle 6

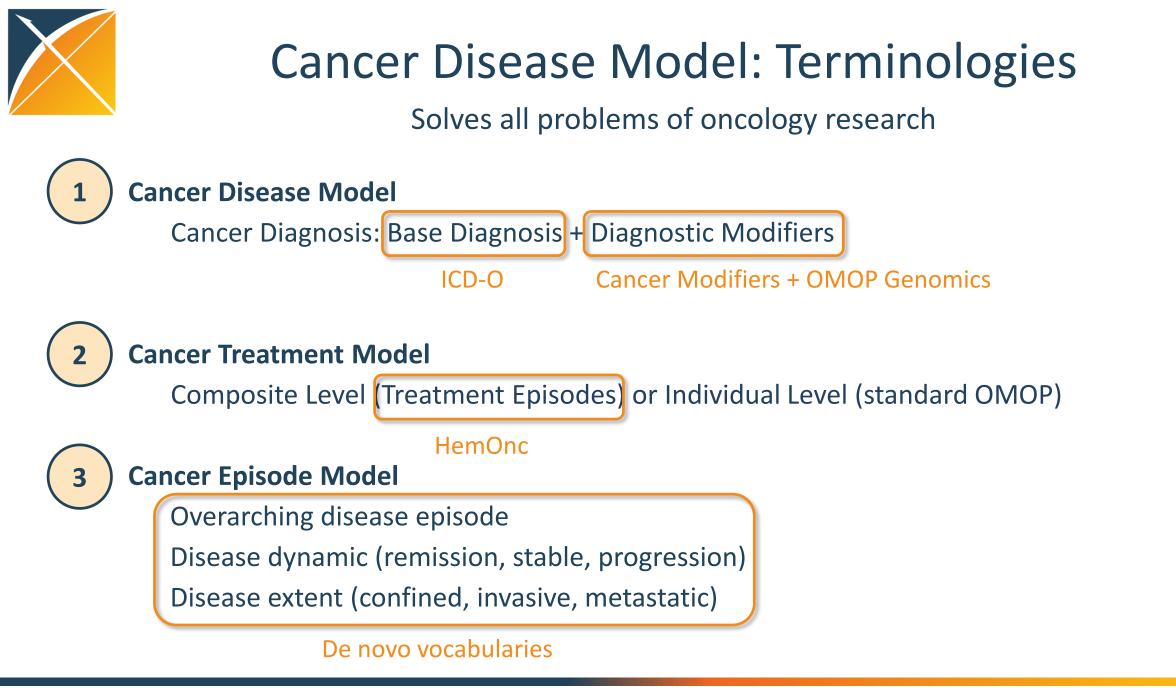


Episodes

- ✓ Continuous periods of disease or treatment with distinct clinical meaning
- ✓ Composed of multiple events
- ✓ Essential for conducting cancer research
- ✓ Obtained directly from source data (e.g., registries) or algorithmically derived
- Parent Episode:
 - Overarching disease episode: Covers the entire cancer duration
- Children Episodes:
 - **Disease dynamic** (remission, stable, progression)
 - **Disease extent** (confined, invasive, metastatic)

Cancer Episode Model: Schematic Patient Journey







Genomic Variants are not Features

Without features, epidemiological methods cannot work

Genomic markers need to be turned into features of an analytical dataset:

Met exon 14 skipping mutation

- Splice region variant
- Chromosome 7q31.2
- Exon 14 missing
- Location 116411884-116411895

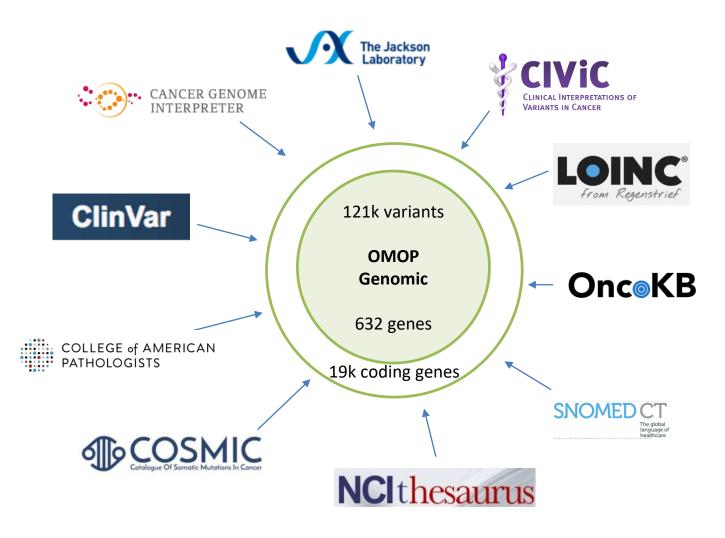
	Feature 1	Feature 2	Feature 3	Feature 4	Feature 5	Feature 6	Feature 7	Feature 8	Feature 9	Feature 10	Feature 11	Feature 12
Person 1												
Person 2												
Person 3												
Person 4												
Person 5												
Person 6												
Person 7												
Person 8					1							
Person 9												
Person 10												
Person 11												
Person 12												
Person 13											1	
Person 14												
Person 15												
Person 16												
Person 17		1										
Person 18												



OMOP Genomic is built from relevant sources

... by

- Combining public repositories
- Deduping them





Oncology module enables observational cancer study in a network setting



We can study

Diagnosis Prognosis

Tx outcome

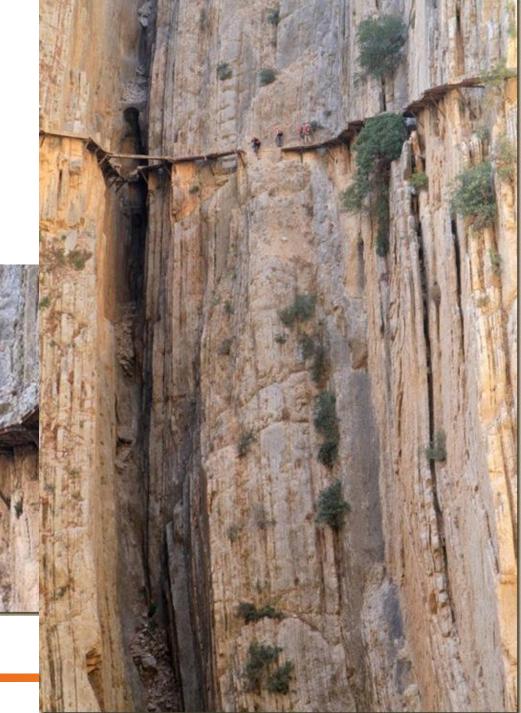
Incidence Disease biology · Prevalence • Tumor burden Tumor evolution Screening utility • Biomarker significance Mortality Response rate Overall survival Progression-free survival Treatment utilization Utilization Utilization Utilization of new tests

In populations with..

- Stage
- Grade
- Dimension of tumor
- Extension of tumor
- Tumor margin
- Remission, stable or progressive disease
- Regimen
- Lines of therapy
- Diagnostic biomarker
- Prognostic biomarker
- Predictive biomarker
- .. with speed, at scale

Don't create your own data model







Building the Future of Observational Cancer Research Together

Open Research Network at inception

Open Research Network at scale

