



Phenotype Aphril: The Phoundation of Reliable Real World Evidence

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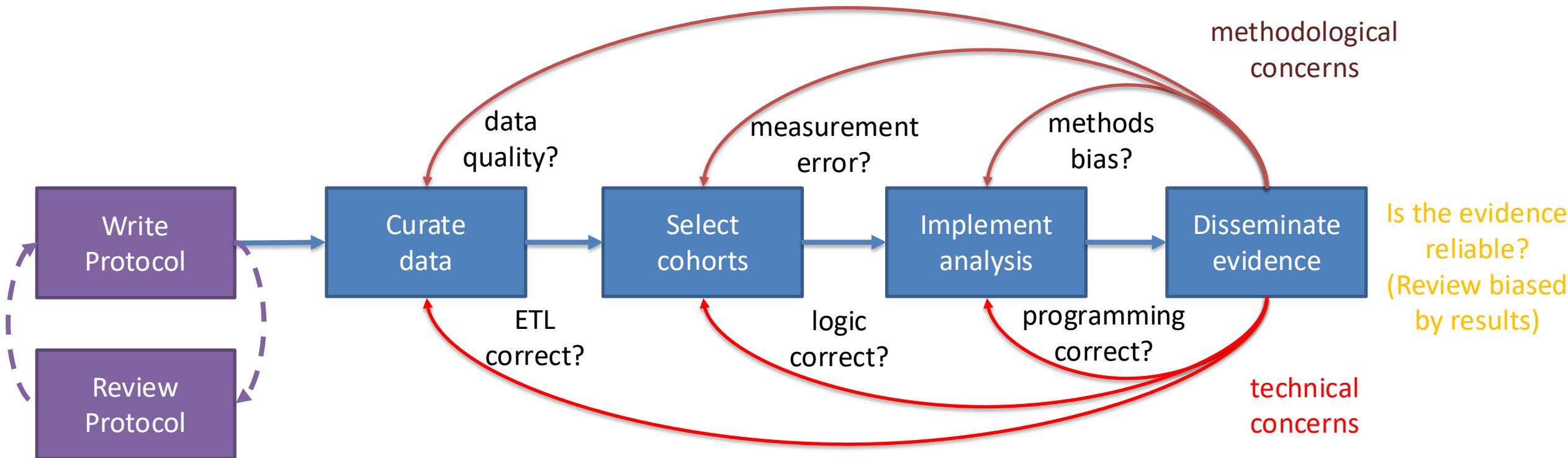
OHDSI's mission

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



Current status quo in observational research makes it challenging to build trust in evidence

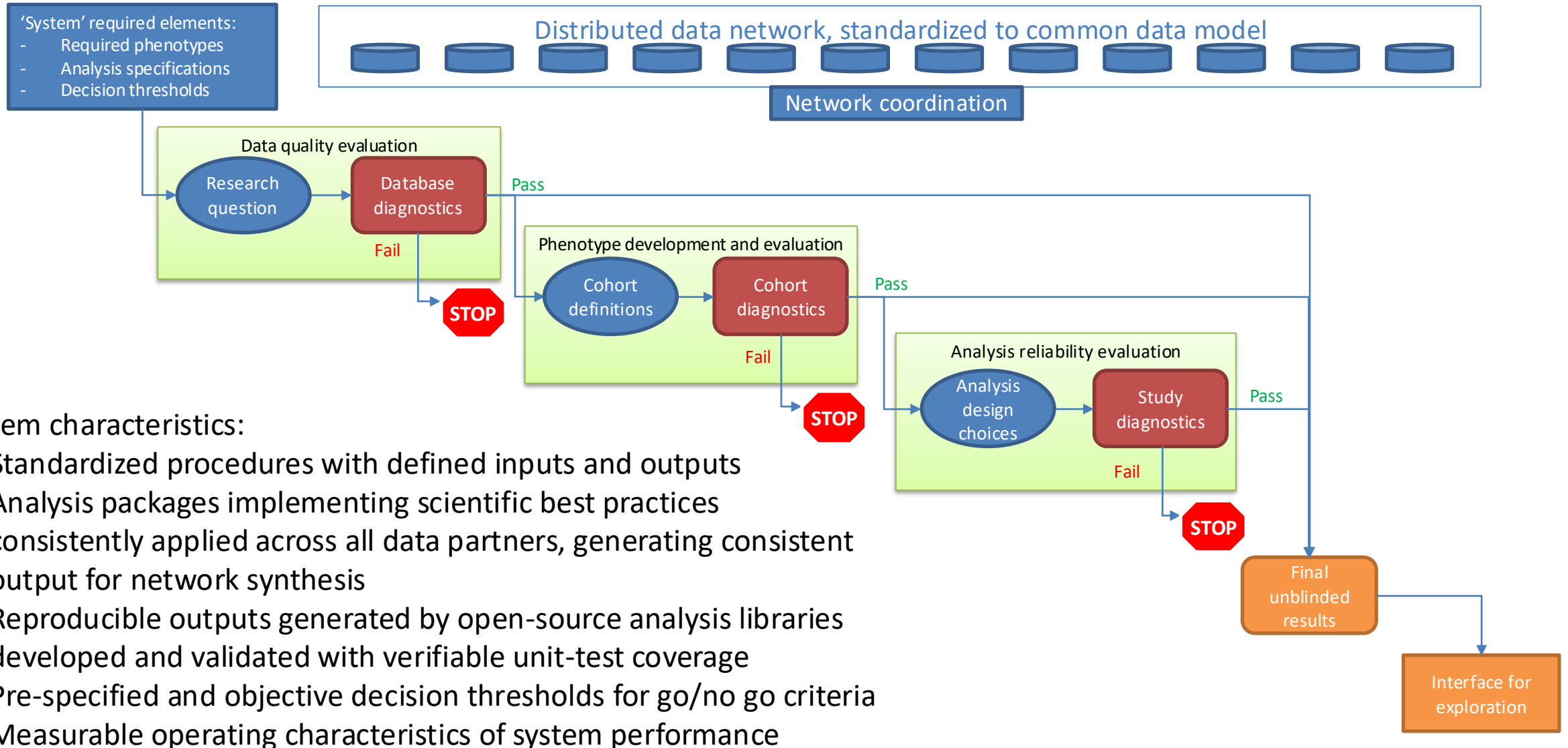
Does the study provide an unbiased effect estimate?
Are the findings generalizable to the population of interest?



Can the study be fully reproduced?
Does the analysis actually do what the protocol said it would do?



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

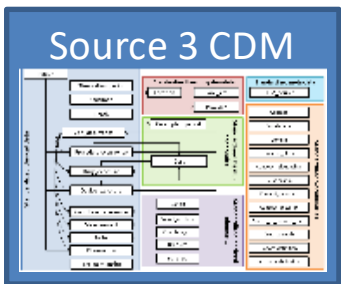
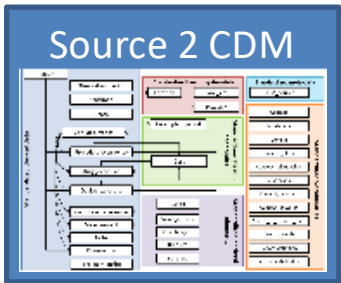
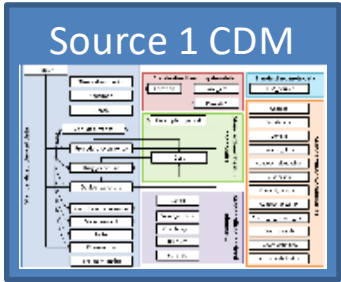


| Analytic use case | Type | Structure | Example |
|------------------------------------|-------------------------------|--|---|
| Clinical characterization | Disease Natural History | Amongst patients who are diagnosed with <insert your favorite disease>, what are the patient's characteristics from their medical history? | Amongst patients with rheumatoid arthritis , what are their demographics (age, gender), prior conditions, medications, and health service utilization behaviors? |
| | Treatment utilization | Amongst patients who have <insert your favorite disease>, which treatments were patients exposed to amongst <list of treatments for disease> and in which sequence? | Amongst patients with depression , which treatments were patients exposed to SSRI, SNRI, TCA, bupropion, esketamine and in which sequence? |
| | Outcome incidence | Amongst patients who are new users of <insert your favorite drug>, how many patients experienced <insert your favorite known adverse event from the drug profile> within <time horizon following exposure start>? | Amongst patients who are new users of methylphenidate , how many patients experienced psychosis within 1 year of initiating treatment ? |
| Population-level effect estimation | Safety surveillance | Does exposure to <insert your favorite drug> increase the risk of experiencing <insert an adverse event> within <time horizon following exposure start>? | Does exposure to ACE inhibitor increase the risk of experiencing Angioedema within 1 month after exposure start ? |
| | Comparative effectiveness | Does exposure to <insert your favorite drug> have a different risk of experiencing <insert any outcome (safety or benefit) > within <time horizon following exposure start>, relative to <insert your comparator treatment>? | Does exposure to ACE inhibitor have a different risk of experiencing acute myocardial infarction while on treatment , relative to thiazide diuretic ? |
| Patient level prediction | Disease onset and progression | For a given patient who is diagnosed with <insert your favorite disease>, what is the probability that they will go on to have <another disease or related complication> within <time horizon from diagnosis>? | For a given patient who is newly diagnosed with atrial fibrillation , what is the probability that they will go onto to have ischemic stroke in next 3 years ? |
| | Treatment response | For a given patient who is a new user of <insert your favorite chronically-used drug>, what is the probability that they will <insert desired effect> in <time window>? | For a given patient with T2DM who start on metformin , what is the probability that they will maintain HbA1C<6.5% after 3 years ? |
| | Treatment safety | For a given patient who is a new user of <insert your favorite drug>, what is the probability that they will experience <insert adverse event > within <time horizon following exposure>? | For a given patients who is a new user of warfarin , what is the probability that they will have GI bleed in 1 year ? |

The journey to evidence

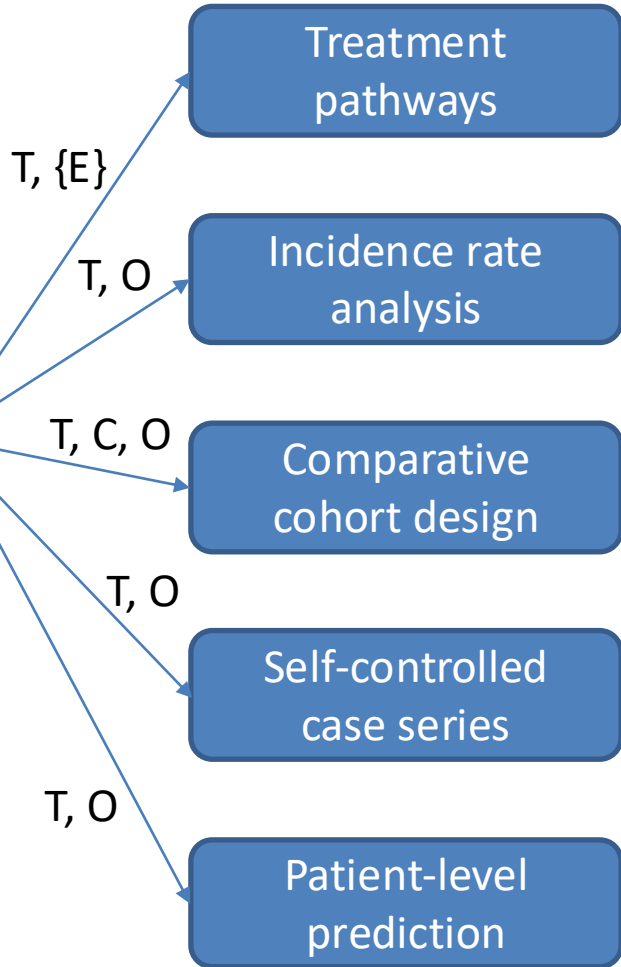


Standardized data

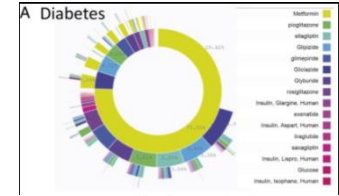


Cohort definition:
a specification to
identify the set of
persons satisfying one
or more criteria for a
duration of time

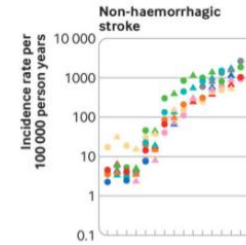
Standardized analytics



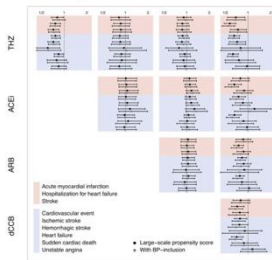
Impactful results



Hripcsak et al
PNAS 2016



Li et al
BMJ 2021



Suchard et al
Lancet 2019

S10. Self-controlled case series results for hydroxychloroquine
S10.1. CCAE

| Outcome | Analysis | Cases | IRR | 95% CI LB | 95% CI UB | Calibrated I | Calibrated IRR | Calibrated 95% CI LB | Calibrated 95% CI UB |
|---------------------------|---|--------|------|-----------|-----------|--------------|----------------|----------------------|----------------------|
| Myocardial infarction | Adjusting for event-dependent observation | 14,483 | 0.91 | 0.83 | 0.99 | 0.53 | 0.91 | 0.89 | 1.21 |
| | Primary analysis | 14,483 | 0.91 | 0.84 | 1 | 0.87 | 0.92 | 0.7 | 1.22 |
| Acute pancreatitis events | Adjusting for event-dependent observation | 13,221 | NA | NA | NA | NA | NA | NA | NA |
| | Primary analysis | 13,221 | 0.89 | 0.81 | 0.99 | 0.48 | 0.9 | 0.88 | 1.2 |
| Acute renal failure | Adjusting for event-dependent observation | 17,178 | 0.89 | 0.82 | 0.98 | 0.38 | 0.89 | 0.87 | 1.16 |
| | Primary analysis | 17,178 | 0.9 | 0.84 | 0.96 | 0.47 | 0.9 | 0.89 | 1.19 |

Lane et al Lancet
Rheumatology 2020



Williams et al
BMC MRM 2022



OHDSI's definition of 'cohort'

Cohort = a set of persons who satisfy one or more inclusion criteria for a duration of time

Cohort era = a continuous period during which a person has satisfied a cohort's inclusion criteria

Two cohorts, each uniquely identified by COHORT_DEFINITION_ID, containing a set of cohort eras

| | COHORT_DEFINITION_ID | SUBJECT_ID | COHORT_START_DATE | COHORT_END_DATE |
|----------|----------------------|------------|-------------------|-----------------|
| COHORT 1 | 1 | 1234 | 3/14/2014 | 4/30/2014 |
| | 1 | 1234 | 12/1/2014 | 2/18/2015 |
| | 1 | 3456 | 1/28/2016 | 10/7/2016 |
| | 1 | 2345 | 9/22/2017 | 11/17/2017 |
| | 1 | 3467 | 8/13/2016 | 3/1/2017 |
| COHORT 2 | 2 | 8734 | 1/24/2016 | 7/23/2016 |
| | 2 | 4432 | 11/20/2016 | 6/6/2017 |
| | 2 | 2473 | 5/30/2017 | 12/29/2017 |
| | 2 | 1234 | 4/30/2015 | 7/4/2015 |
| | 2 | 3467 | 1/12/2015 | 8/24/2015 |
| | 2 | 4572 | 4/4/2016 | 3/8/2017 |



OHDSI's definition of 'cohort'

Cohort = a set of persons who satisfy one or more inclusion criteria for a duration of time

Cohort era = a continuous period during which a person has satisfied a cohort's inclusion criteria

Cohort definition = the specification for how to identify a cohort

A codeset is NOT a cohort...

...logic for how to use the codes in criteria is required



OHDSI's definition of 'cohort'

Cohort = a set of persons who satisfy one or more inclusion criteria for a duration of time

Cohort era = a continuous period during which a person has satisfied a cohort's inclusion criteria

| COHORT_DEFINITION ID | SUBJECT ID | COHORT_START DATE | COHORT_END DATE | |
|----------------------|------------|-------------------|-----------------|--------|
| 1 | 1234 | 3/14/2014 | 4/30/2014 | ERA 1 |
| 1 | 1234 | 12/1/2014 | 2/18/2015 | ERA 2 |
| 1 | 3456 | 1/28/2016 | 10/7/2016 | ERA 3 |
| 1 | 2345 | 9/22/2017 | 11/17/2017 | ERA 4 |
| 1 | 3467 | 8/13/2016 | 3/1/2017 | ERA 5 |
| 2 | 8734 | 1/24/2016 | 7/23/2016 | ERA 6 |
| 2 | 4432 | 11/20/2016 | 6/6/2017 | ERA 7 |
| 2 | 2473 | 5/30/2017 | 12/29/2017 | ERA 8 |
| 2 | 1234 | 4/30/2015 | 7/4/2015 | ERA 9 |
| 2 | 3467 | 1/12/2015 | 8/24/2015 | ERA 10 |
| 2 | 4572 | 4/4/2016 | 3/8/2017 | ERA 11 |

11 cohorts eras, each record in the COHORT table uniquely identifies a period of time a person satisfies cohort criteria



Consequences of OHDSI's definition of cohort

Cohort = a set of persons who satisfy one or more inclusion criteria for a duration of time

Cohort era = a continuous period during which a person has satisfied a cohort's inclusion criteria

One cohort may have zero or more eras

- COHORT 1 has 5 eras
- COHORT 2 has 6 eras
- COHORT 3 has 0 eras

One person may belong to multiple cohorts

- Persons 1234 and 3467 both belong to COHORT 1 and 2

| COHORT_DEFINITION ID | SUBJECT ID | COHORT_START DATE | COHORT_END DATE |
|----------------------|------------|-------------------|-----------------|
| 1 | 1234 | 3/14/2014 | 4/30/2014 |
| 1 | 1234 | 12/1/2014 | 2/18/2015 |
| 1 | 3456 | 1/28/2016 | 10/7/2016 |
| 1 | 2345 | 9/22/2017 | 11/17/2017 |
| 1 | 3467 | 8/13/2016 | 3/1/2017 |
| 2 | 8734 | 1/24/2016 | 7/23/2016 |
| 2 | 4432 | 11/20/2016 | 6/6/2017 |
| 2 | 2473 | 5/30/2017 | 12/29/2017 |
| 2 | 1234 | 4/30/2015 | 7/4/2015 |
| 2 | 3467 | 1/12/2015 | 8/24/2015 |
| 2 | 4572 | 4/4/2016 | 3/8/2017 |

One person may belong to the same cohort at multiple different time periods

- Person 1234 has two eras in COHORT 1

One person may not belong to the same cohort multiple times during the same period of time (e.g. eras do not overlap)



OHDSI open-source community tools to support phenotype development and evaluation process

Phenotype definition tools:

- ATLAS
 - Concept set expressions – with recommendations from PHOEBE2.0
 - Cohort Definitions – to design a rule-based cohort definition
 - Profiles – to review individual cases
- CapR - cohort definition application programming in R, to design rule-based cohort definitions consistent with CIRCE JSON specifications
- APHRODITE - to develop a probabilistic phenotype by training a prediction model using noisy labels

Phenotype evaluation tools:

- CohortDiagnostics – to evaluate phenotype algorithms using population-level characterization to identify sensitivity/specificity errors and index date misspecification
- PheValuator - to evaluate a phenotype algorithm (estimate sensitivity/specificity/PPV) by training a prediction model and creating a probabilistic reference standard
- KEEPER – An R package for reviewing patient profiles for phenotype validation, through human or LLM-assisted case adjudication

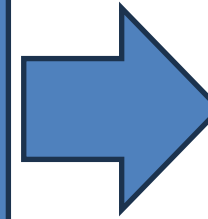
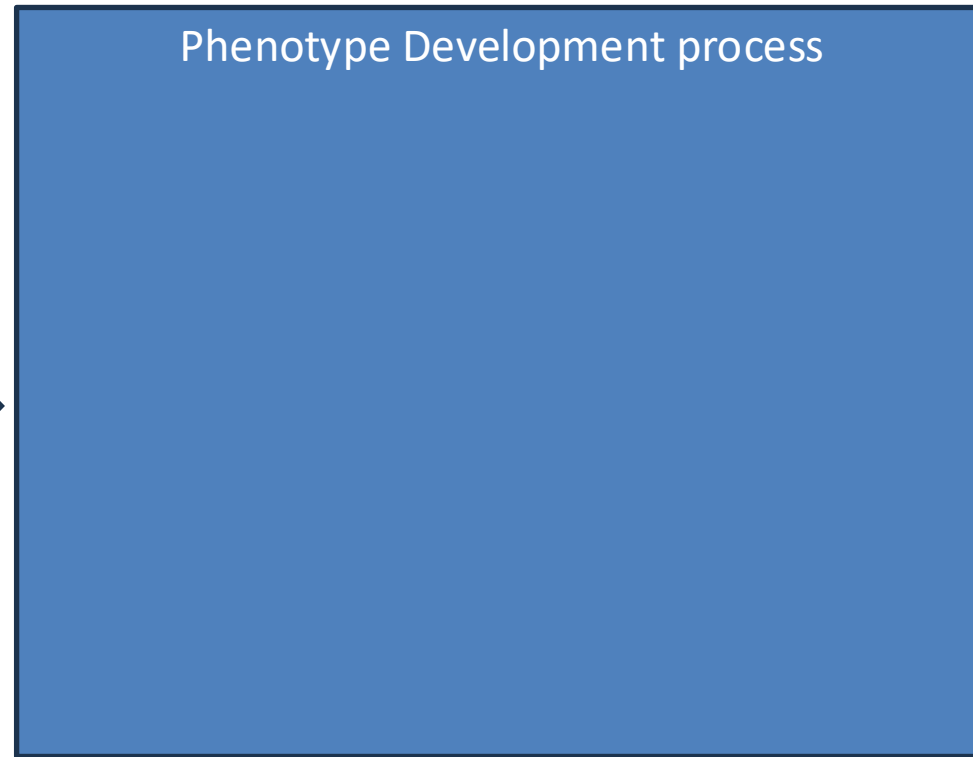
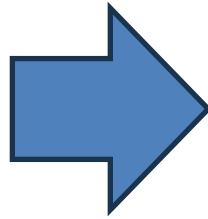
Phenotype Library





Phenotype Development

Inputs:
• Clinical idea



Outputs:
• Cohort definition





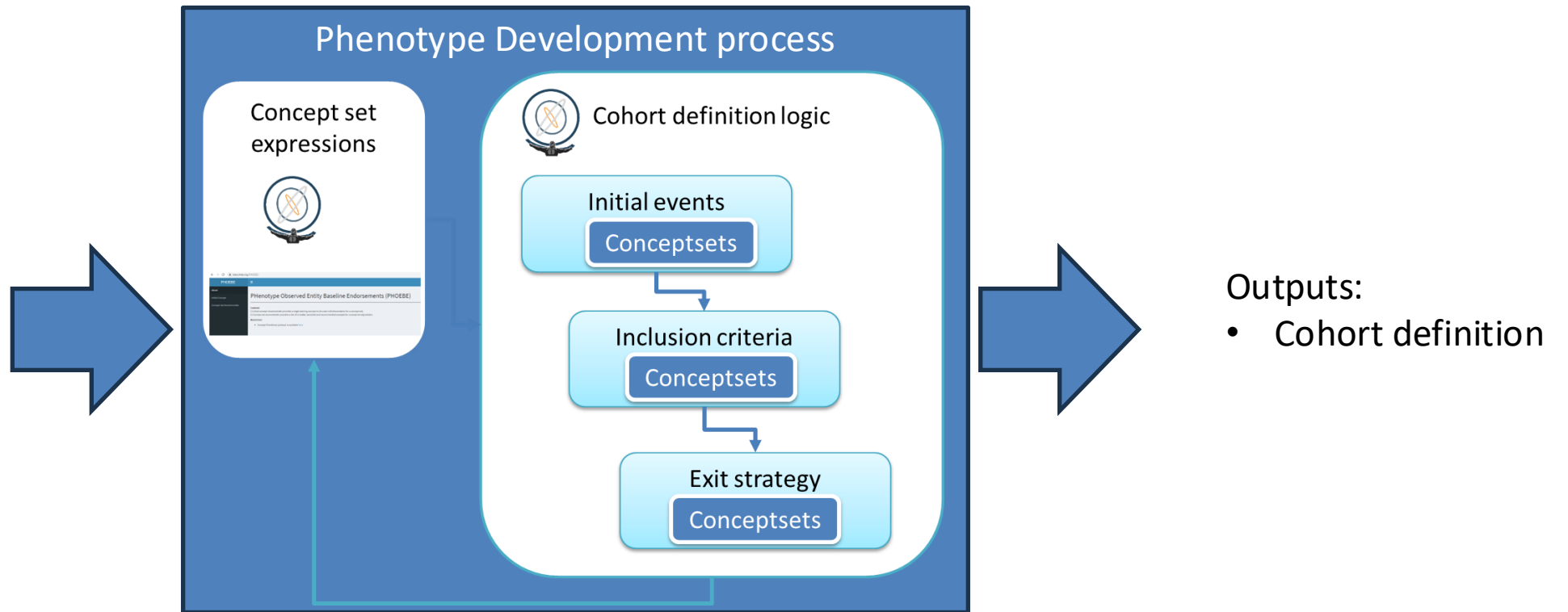
Steps for developing phenotypes with evaluation in mind

1. Identify the persons who might have the disease
 - Aim: Increase sensitivity
 - Task: Create inclusive conceptsets used in cohort entry events
2. Restrict persons who likely do not have disease
 - Aim: Increase specificity / positive predictive value
 - Task: Add inclusion criteria
3. Determine the start and end dates for each disease episode
 1. Aim: Reduce index date misspecification
 2. Task: Set exit strategy, refine entry events and inclusion criteria



Phenotype Development

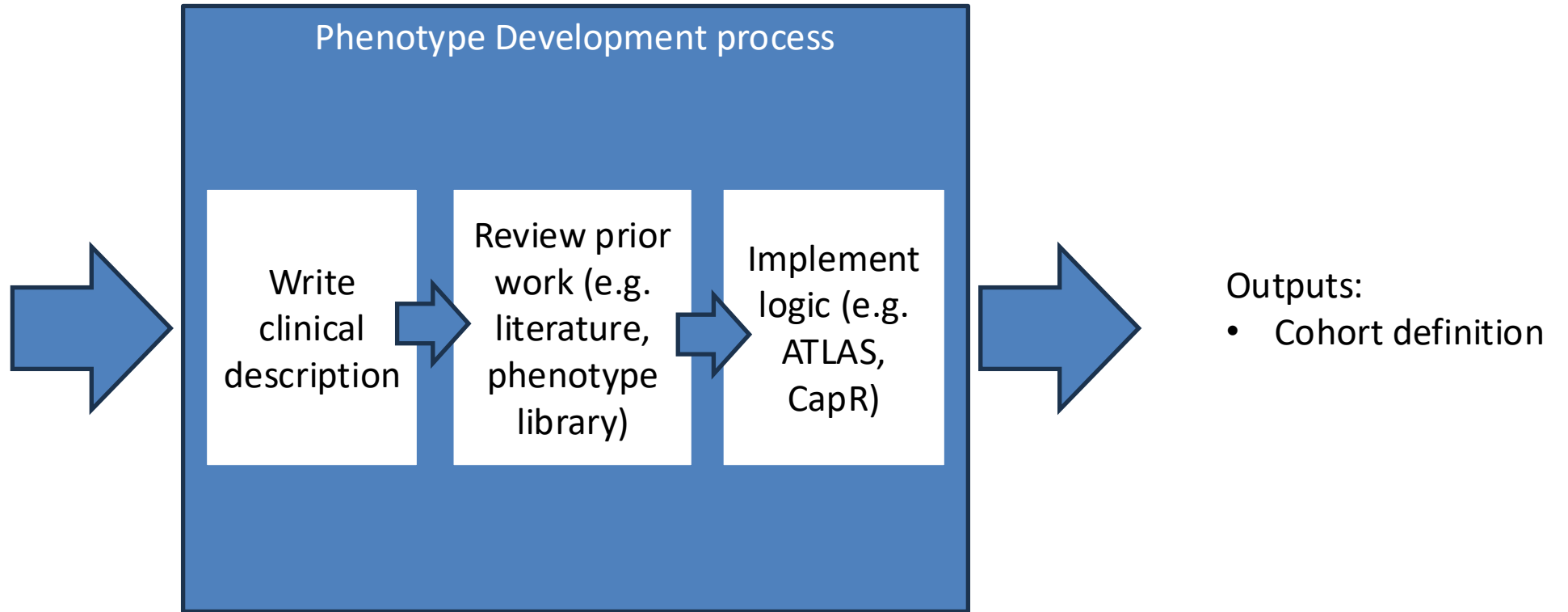
Inputs:
• Clinical idea





Phenotype Development

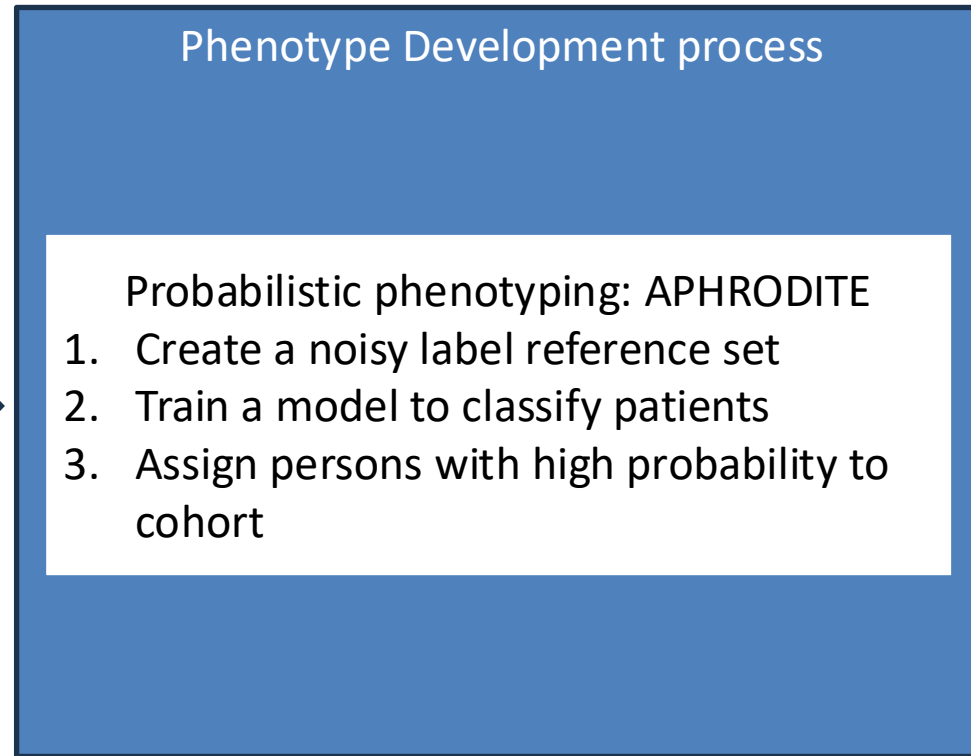
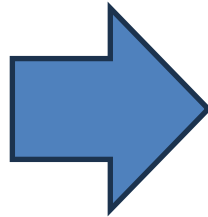
Inputs:
• Clinical idea





Phenotype Development

Inputs:
• Clinical idea

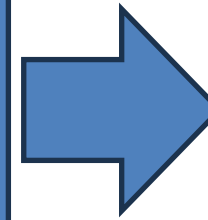
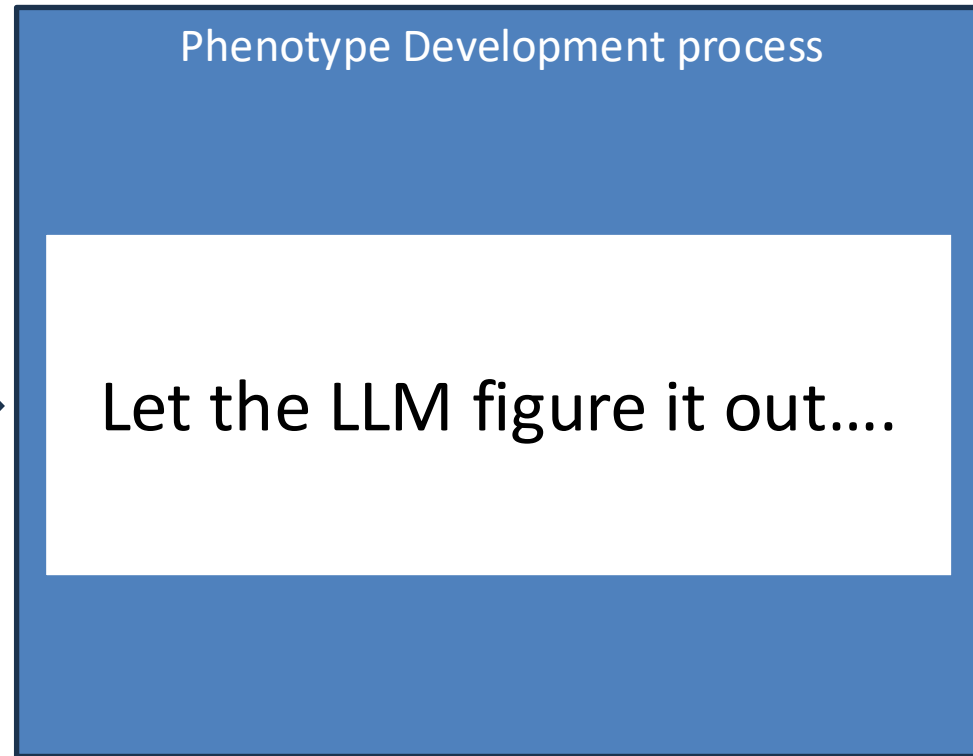
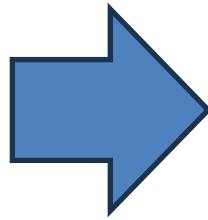


Outputs:
• Cohort definition



Phenotype Development

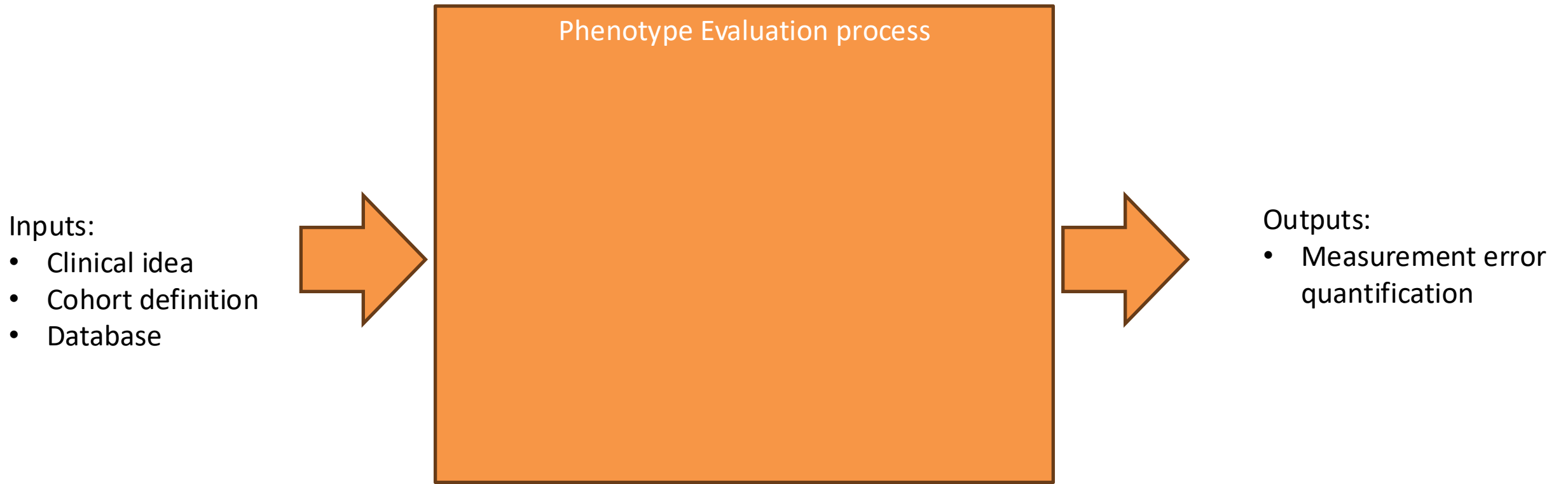
Inputs:
• Clinical idea



Outputs:
• Cohort definition



Phenotype Evaluation





Evaluating phenotypes

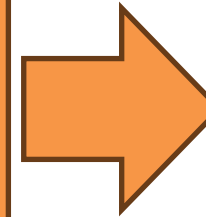
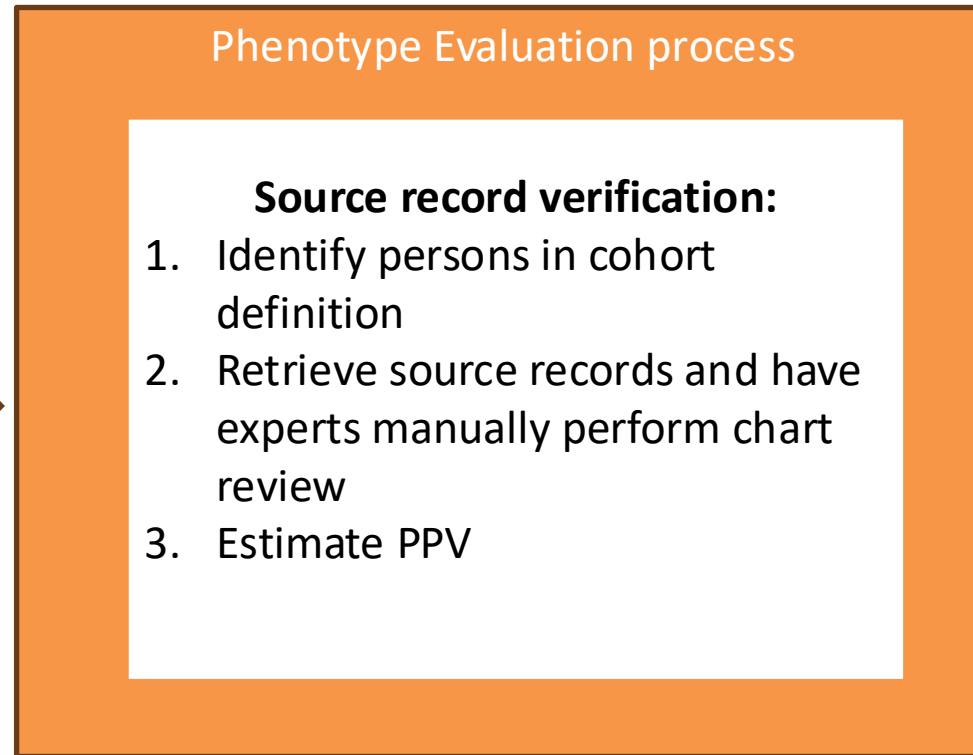
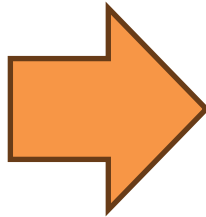
- Objective: estimate the extent to which the inference from the phenotype algorithm consistent with the true health state of the patients?
- Measurement error measures:
 - Sensitivity, specificity, positive predictive value, negative predictive value
- ‘A phenotype is fit-for-use’ = The measurement error of the phenotype in the dataset is sufficiently small that it will not negatively impact the interpretation of analysis results



Phenotype Evaluation

Inputs:

- Clinical idea
- Cohort definition
- Database



Outputs:

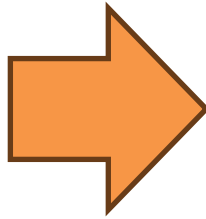
- Measurement error quantification



Phenotype Evaluation

Inputs:

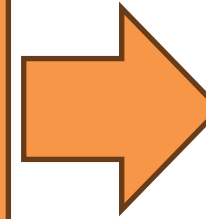
- Clinical idea
- Cohort definition
- Database



Phenotype Evaluation process

PheValuator:

1. Create a noisy label reference set
2. Train a model to classify patients
3. Create an evaluation dataset with probabilities for each patients
4. Compare patients in cohort definition to predicted probabilities to estimate sensitivity, specificity, PPV, NPV



Outputs:

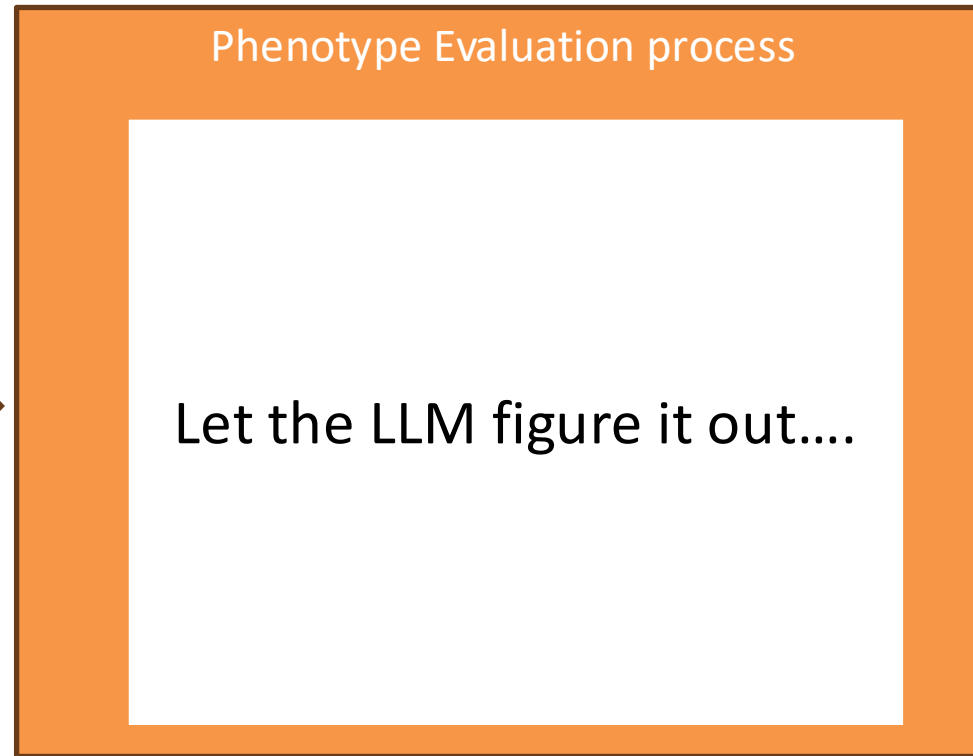
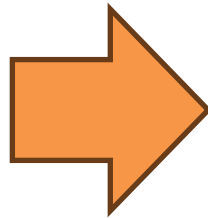
- Measurement error quantification



Phenotype Evaluation

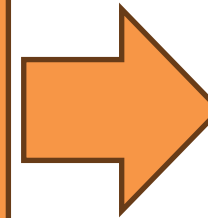
Inputs:

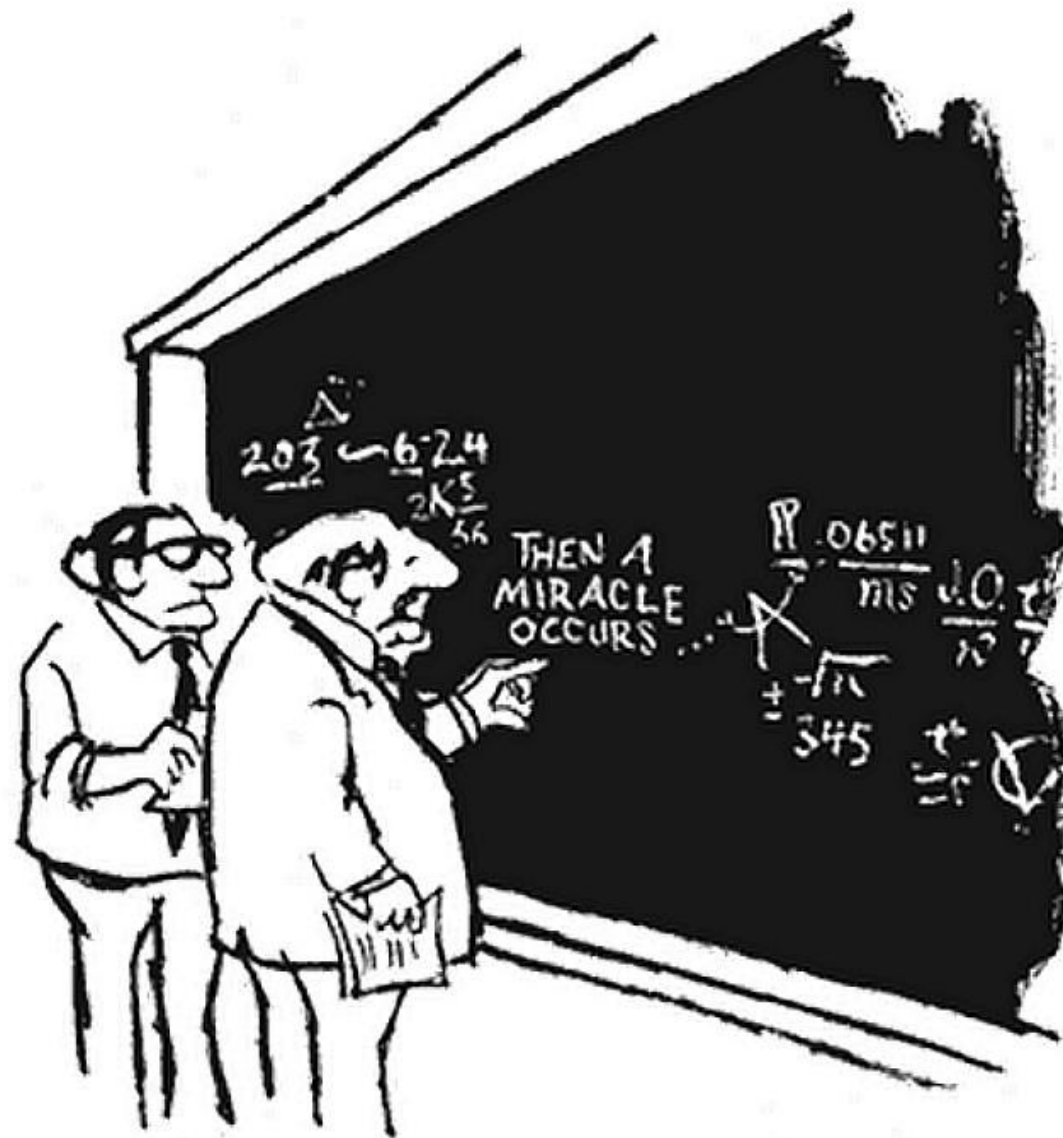
- Clinical idea
- Cohort definition
- Database



Outputs:

- Measurement error quantification





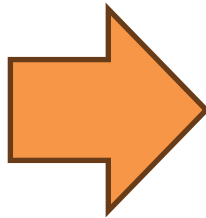
"I THINK YOU SHOULD BE MORE EXPLICIT HERE IN STEP TWO."



Phenotype Evaluation

Inputs:

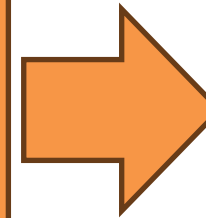
- Clinical idea
- Cohort definition
- Database



Phenotype Evaluation process

KEEPER-LLM:

1. Create structured patient profiles (KEEPER) for persons in and out of cohort definition
2. LLM adjudicates profiles to determine case/non-case status and confidence
3. Compare patients in cohort definition to estimate sensitivity, specificity, PPV, NPV



Outputs:

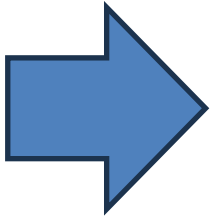
- Measurement error quantification



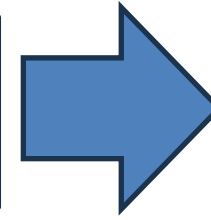
Evaluating the Phenotype Development and Evaluation process

Inputs:

- Clinical idea



Phenotype Development process

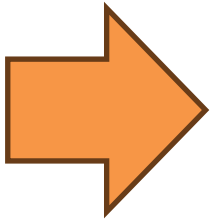


Outputs:

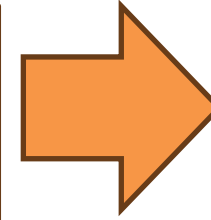
- Cohort definition

Inputs:

- Clinical idea
- Cohort definition
- Database



Phenotype Evaluation process

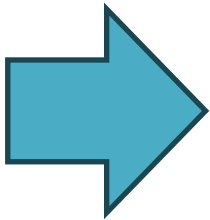


Outputs:

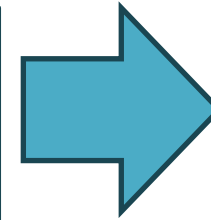
- Measurement error quantification

Inputs:

- Clinical idea
- Cohort definition
- Database
- Measurement error quantification



Phenotype Evaluation Calibration



Outputs:

- Measurement error bias assessment



Let's phenotype Acute Myocardial Infarction...





9:33

Acute Myocardial Infa...

Create a report that summarizes phenotype development and evaluation efforts for acute myocardial infarction in observational healthcare data, such as administrative claims, electronic health records, and national registries. Identify publications and extract the codelists used, the logic for how cases are included or excluded. As well as the approach employed to validate the algorithm. Summarize the most commonly used phenotype algorithms and their measurement error (positive predictive value, sensitivity, specificity). Provide recommendations for how future observational studies should consider phenotyping acute myocardial infarction to achieve a good sensitivity specificity tradeoff, while increasing generalizability to allow for the algorithms application in global network studies, such as

What do you want to research?

Search bar with icons for search, thinking, microphone, and send.

Acute Myocardial Infa...

I've put together a research plan. If you need to update it in any way, let me know.

Acute Myocardial Infarction Phenotyping Report

Research Websites

- (1) Search for peer-reviewed publications and white papers discussing phenotype development and validation for acute myocardial infarction (AMI) in administrative claims and electronic health records (EHRs).
- (2) Identify specific studies from organizations like OHDSI, Sentinel, or PCORnet that focus on standardizing AMI definitions across observational databases.
- (3) Extract technical details from these studies, including specific ICD-9/10 codes, SNOMED codes, and the logic for inclusion (e.g., primary discharge diagnosis, inpatient status) and exclusion (e.g., transfers, prior history within specific lookback windows).
- (4) Investigate the validation methodologies used in these papers, such as manual chart review, comparison against gold-standard registries, or cross-database validation.
- (5) Tabulate the performance metrics (positive predictive value, sensitivity, specificity) reported for the most common AMI algorithms to identify trends in measurement error.

What do you want to research?

Search bar with icons for search, thinking, microphone, and send.

Acute Myocardial Infa...



Start research



I've completed your research. Feel free to ask me follow-up questions or request changes.

Acute Myocardial Infarction Phenotyping Report

Mar 29, 2:20 PM

Open



What do you want to research?

Search bar with icons for search, thinking, microphone, and send.



Phenotype Development and Evaluation for Acute Myocardial Infarction in Observational Healthcare Data

The capacity to accurately identify acute myocardial infarction within large-scale observational healthcare databases is a cornerstone of modern cardiovascular epidemiology and health services research. As clinical practice and data capture mechanisms evolve, the methodologies employed to develop and validate these computational phenotypes have transitioned from simple, single-modality code heuristics to complex, multi-modal algorithms that integrate structured billing data, laboratory measurements, and unstructured clinical narratives. The reliability of real-world evidence generated from these sources is inherently tied to the measurement error of the underlying phenotype algorithms, specifically their sensitivity, specificity, and positive predictive value. In the context of global research networks, such as those facilitated by the Observational Health Data Sciences and Informatics community, the challenge of phenotyping is compounded by variations in regional coding practices, clinical documentation standards, and the underlying technological infrastructure of different healthcare systems.



Clinical Framework and the Impact of the Universal Definition

The phenotypic representation of acute myocardial infarction in observational data is fundamentally governed by the clinical criteria used for diagnosis at the point of care. The fourth universal definition of myocardial infarction introduced a critical distinction between acute myocardial injury and myocardial infarction, a shift that has significant implications for how researchers interpret troponin elevations in electronic health records. Myocardial injury is broadly defined by a rise and/or fall of cardiac troponin values with at least one value exceeding the 99th percentile upper reference limit. However, for a diagnosis of myocardial infarction, this injury must occur in the clinical context of acute myocardial ischemia. This requires additional evidence such as symptoms of ischemia, new ischemic electrocardiogram changes, the development of pathological Q waves, or imaging evidence of new loss of viable myocardium or regional wall motion abnormality.

The physiological heterogeneity captured by these definitions necessitates a granular approach to phenotyping. Acute myocardial infarction is typically categorized into ST-elevation myocardial infarction, non-ST-elevation myocardial infarction, and unstable angina, although the latter is often differentiated by



Recommendations for Future Observational Studies

To achieve a good balance between sensitivity and specificity while ensuring the generalizability of AMI phenotypes in global network studies, future research efforts should adopt a structured, multi-layered approach to phenotype development and evaluation.

Hierarchical and Purpose-Driven Phenotyping

Researchers should avoid the pursuit of a single "perfect" algorithm and instead develop a hierarchy of definitions tailored to specific research questions.

- 1. Safety Surveillance and Adverse Event Detection:** For studies where the primary goal is to minimize false positives, a high-specificity phenotype is recommended. This definition should be restricted to the principal diagnosis position in inpatient settings, require a minimum length of stay of 2 days (unless the patient died), and ideally incorporate a confirmatory procedure code such as PCI or cardiac catheterization.
- 2. Epidemiological Burden and Comparative Effectiveness:** For estimating the total incidence of AMI or for identifying a broad target cohort, a higher-sensitivity phenotype should be used.



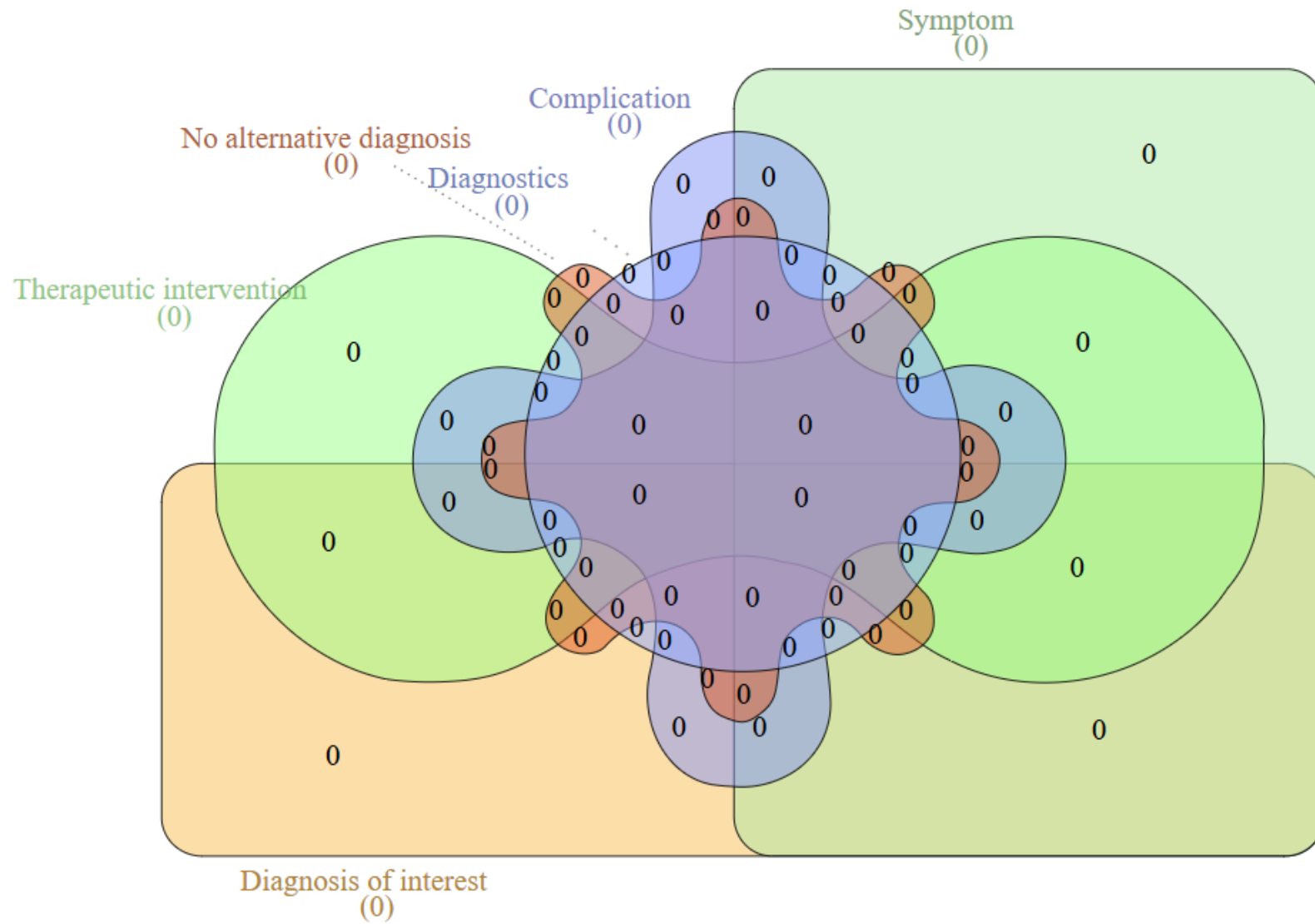
Feel free to read the full LLM report:

<https://g.co/gemini/share/902df1c5668f>



Clinical elements associated with disease status

- **Diagnosis of interest:** 'Acute myocardial infarction'
- **Symptoms:** Chest pain, Difficulty breathing, Sweating, Nausea, ...
- **Diagnostics:**
 - Procedures: Electrocardiography, angiocardiography, ...
 - Measurements: Troponin, creatine kinase, ...
- **Therapeutic interventions:**
 - Drugs: beta blocker, aspirin, heparin, clopidogrel, ...
 - Procedures: percutaneous coronary intervention, coronary artery bypass grafting, insertion of cardiac pacemaker...
- **Complications:** heart failure, cerebral hemorrhage, acute kidney injury, acute pulmonary edema, hepatic failure...
- **Alternative diagnoses:** Aortic aneurysm, panic attack, esophageal reflux...



Heberle, H.; Meirelles, G. V.; da Silva, F. R.; Telles, G. P.; Minghim, R. InteractiVenn: a web-based tool for the analysis of sets through Venn diagrams. *BMC Bioinformatics* 16:169 (2015). [10.1186/s12859-015-0611-3](https://doi.org/10.1186/s12859-015-0611-3)



ATLAS

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[PhenotypeApril] persons with acute myocardial infarction

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Enter a cohort definition description here

Cohort Entry Events

Events having any of the following criteria:

a condition occurrence of **Diagnosis of interest**

a condition occurrence of **Symptoms**

a procedure occurrence of **diagnostic procedures and mea...**

a measurement of **diagnostic procedures and mea...**

a drug exposure of **therapeutic interventions - drug...**

a procedure occurrence of **therapeutic interventions - drug...**

a condition occurrence of **complications**



Inclusion Criteria



New inclusion criteria

1. has diagnosis of interest

2. has symptom

3. has diagnostic procedure or measurement

4. has therapeutic intervention - drug or procedure

5. has follow-up care or complication

6. has no alternative diagnoses

7. has 2+ categories

8. has 3+ categories

9. has 4+ categories

10. has 5+ categories

has diagnosis of interest

Copy

Delete

enter an inclusion rule description

having of the following criteria:

+ Add criteria to group... ▾

with using all occurrences of:

a condition occurrence of

+ Add attribute... ▾

where between

days and days [add additional constraint](#)

The index date refers to the event from the Cohort Entry criteria.

restrict to the same visit occurrence

allow events from outside observation period

Delete Criteria





Inclusion Report for **Optum Extended DoD (v3787)** using 1 event per person

| | Match Rate | Matches | Total Events |
|---------------------|------------|---------|--------------|
| Summary Statistics: | 0.18% | 123,234 | 68,218,480 |

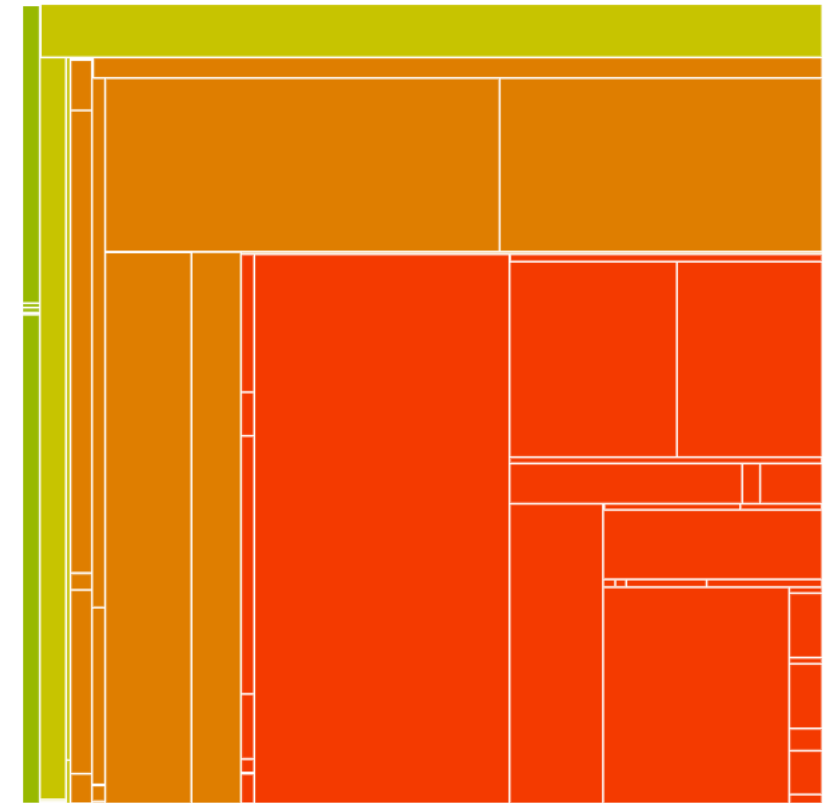
Having of selected criteria

| <input checked="" type="checkbox"/> | Inclusion Rule | N | % Satisfied | % To-Gain |
|-------------------------------------|---|------------|-------------|-----------|
| <input checked="" type="checkbox"/> | 1. has diagnosis of interest | 1,529,357 | 2.24% | 0.83% |
| <input checked="" type="checkbox"/> | 2. has symptom | 59,083,628 | 86.61% | 0.01% |
| <input checked="" type="checkbox"/> | 3. has diagnostic procedure or measurement | 39,491,240 | 57.89% | 0.00% |
| <input checked="" type="checkbox"/> | 4. has therapeutic intervention - drug or procedure | 32,715,153 | 47.96% | 0.01% |
| <input checked="" type="checkbox"/> | 5. has follow-up care or complication | 17,155,854 | 25.15% | 0.01% |
| <input checked="" type="checkbox"/> | 6. has no alternative diagnoses | 41,217,790 | 60.42% | 1.35% |
| <input checked="" type="checkbox"/> | 7. has 2+ categories | 67,909,815 | 99.55% | 0.00% |
| <input checked="" type="checkbox"/> | 8. has 3+ categories | 61,289,210 | 89.84% | 0.00% |
| <input checked="" type="checkbox"/> | 9. has 4+ categories | 25,766,487 | 37.77% | 0.00% |
| <input checked="" type="checkbox"/> | 10. has 5+ categories | 6,106,186 | 8.95% | 0.00% |

Summary: 68,218,480 events (100.00%)

Population Visualization

[Switch to attrition view](#)





Inclusion Report for **Optum Extended DoD (v3787)** using 1 event per person

| | Match Rate | Matches | Total Events |
|---------------------|------------|---------|--------------|
| Summary Statistics: | 0.18% | 123,234 | 68,218,480 |

| Inclusion Rule | N | % Remain | % Diff |
|---|-----------|----------|--------|
| 1. has diagnosis of interest | 1,529,357 | 2.24% | 97.76% |
| 2. has symptom | 1,509,415 | 2.21% | 0.03% |
| 3. has diagnostic procedure or measurement | 1,490,217 | 2.18% | 0.03% |
| 4. has therapeutic intervention - drug or procedure | 1,408,301 | 2.06% | 0.12% |
| 5. has follow-up care or complication | 1,378,310 | 2.02% | 0.04% |
| 6. has no alternative diagnoses | 123,234 | 0.18% | 1.84% |

Attrition Visualization

[Switch to intersect view](#)





Plans for Phenotype April

- Week 1: Phenotype development
 - April 7 community call: Demo – building cohorts in ATLAS
- Week 2: Phenotype evaluation
 - April 14 community call: Interactive – case adjudication using KEEPER
- Week 3: Iterative phenotype development
 - No community call: build your own AMI cohort definitions!
- Week 4: Iterative phenotype evaluation
 - April 28 community call: Review performance of submitted AMI cohort definitions



Join the Journey!

<https://www.ohdsi.org/join-the-journey/>

Looking forward to collaborating with all of you!

Email me: ryan@ohdsi.org