



JOHNS HOPKINS
M E D I C I N E

Best Practices for Secondary Use

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How

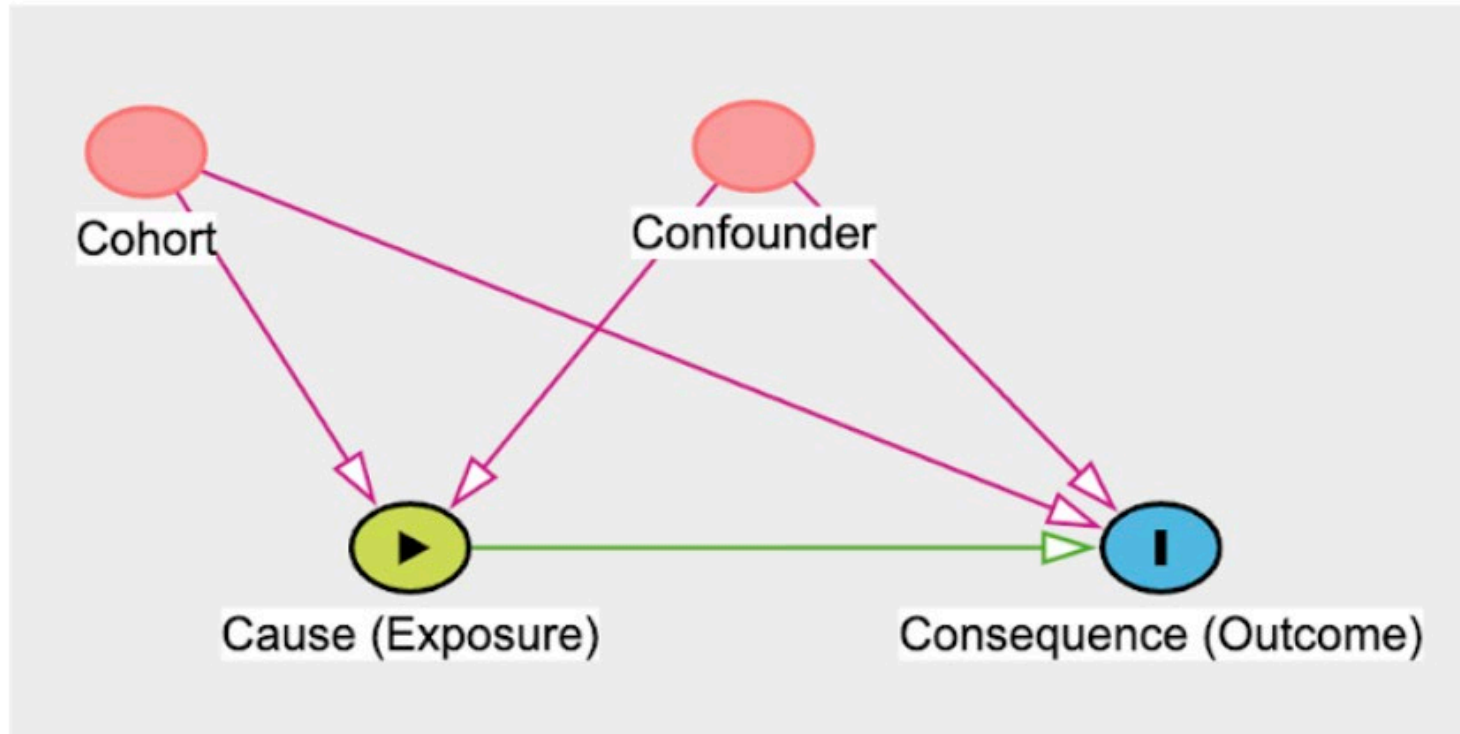
- Methodology
- Reporting
- National Efforts
- Computable

Methodological Considerations

PRIMARY	SECONDARY (RWE)
Hypothesis-based	Hypothesis + Generative
Bespoke data collection	Ad hoc data collection
Pre-data collection analytic plan	Post-data collection analytic plan
Design minimizes biases	Data collection maximizes biases
Established rules	Evolving rules
∴ We know what is definitive	∴ We are not sure what is definitive

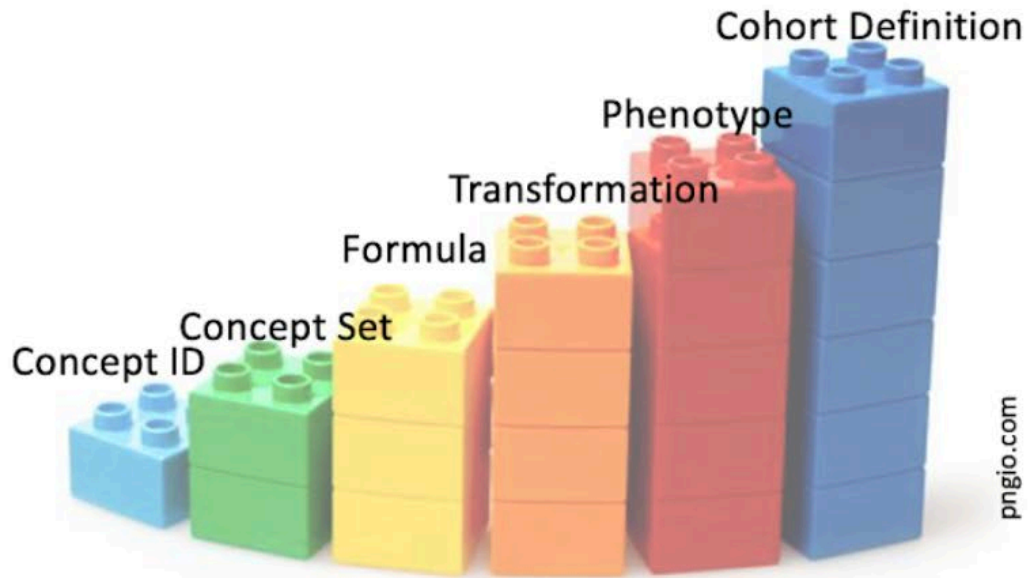
Pre-Data Collection Analytic Plan

Analytic Variables

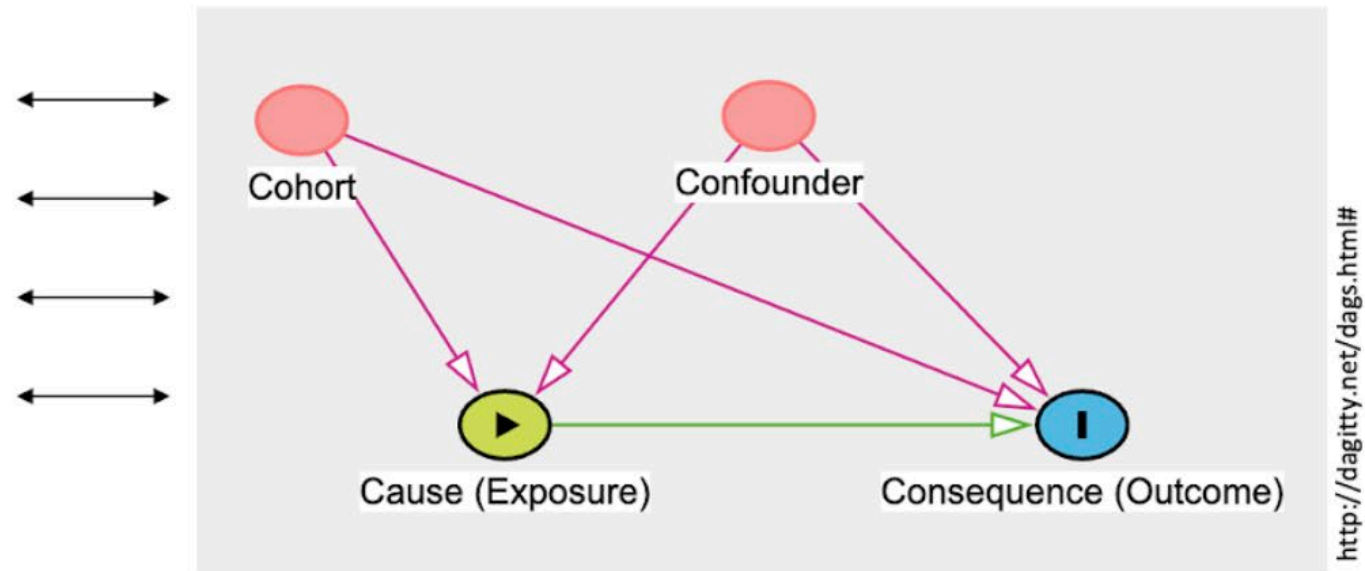


Post-Data Collection Analytic Plan

Data Constructs

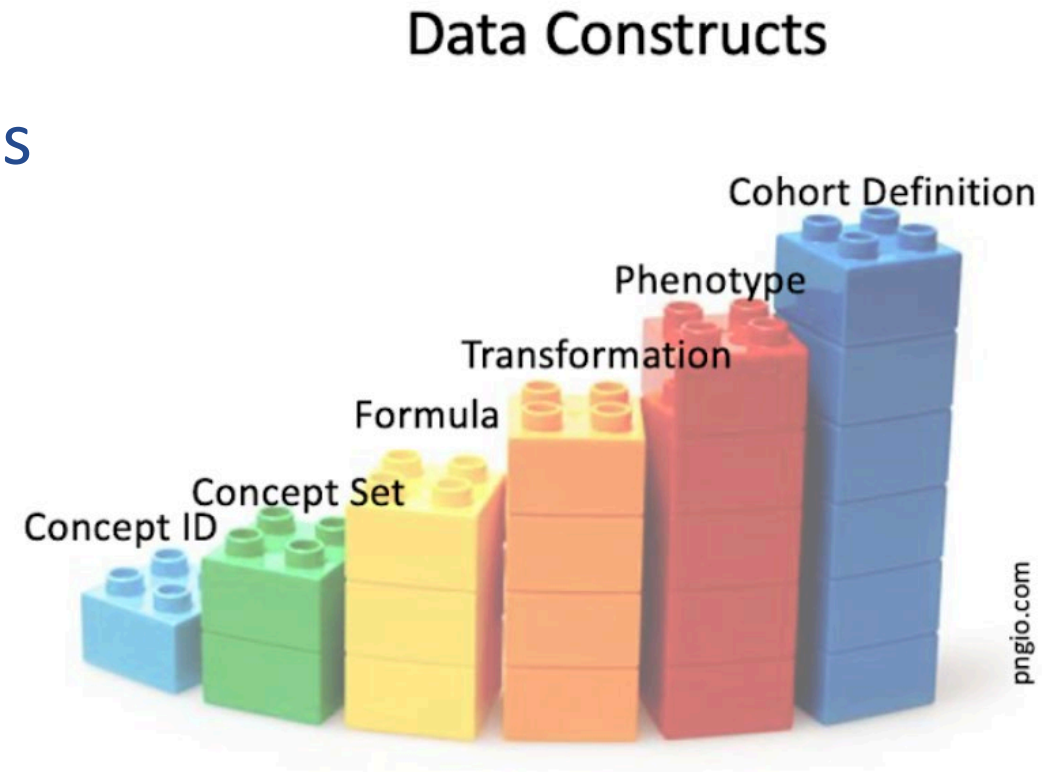


Analytic Variables

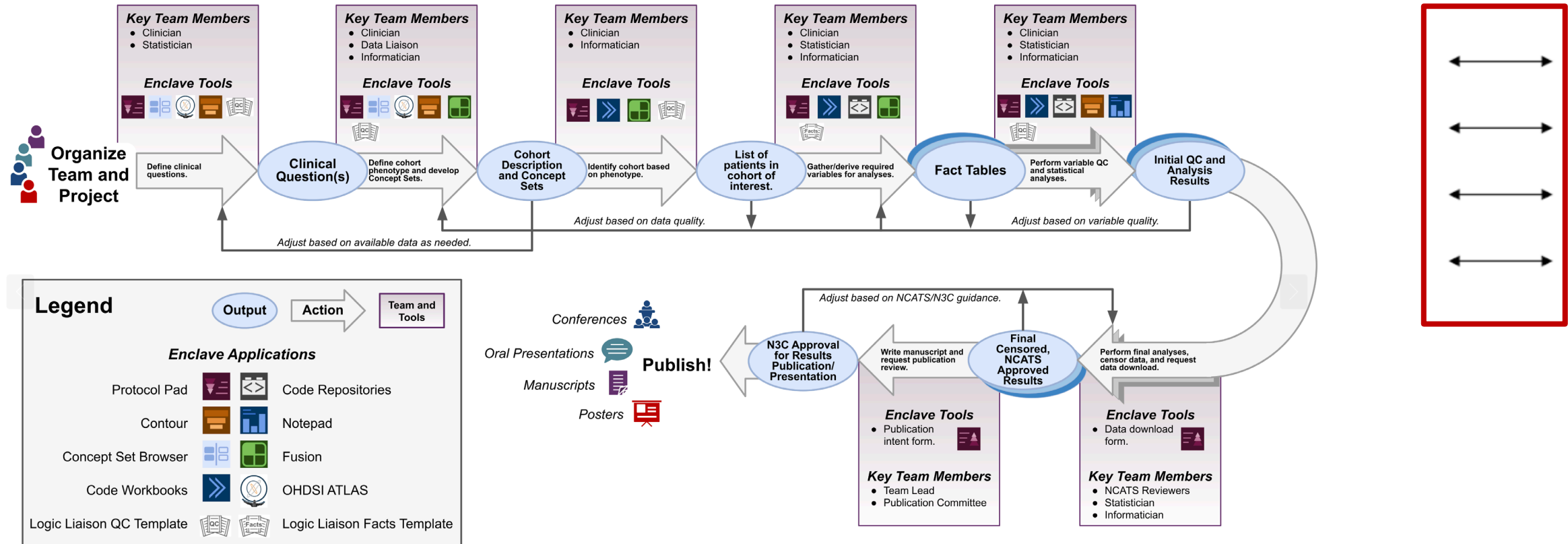


Data Constructs

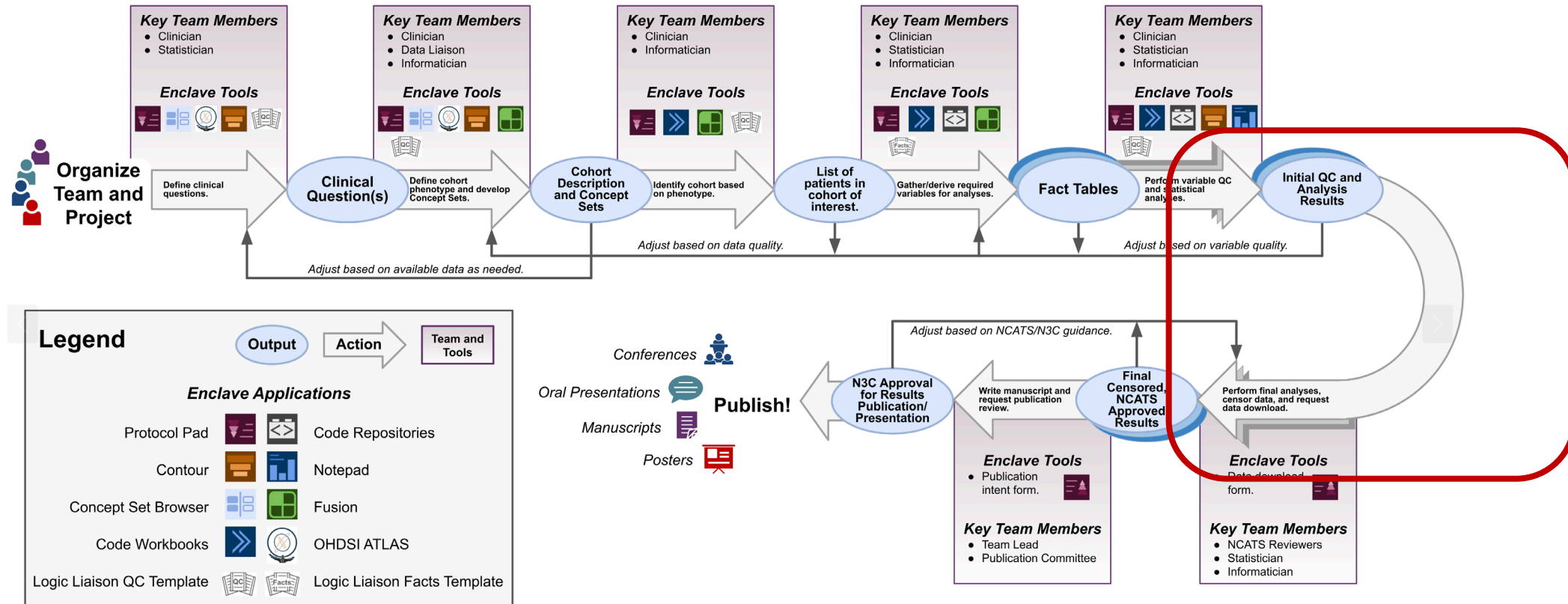
- *Concept ID* Standard code for a datum
- *Concept Set* Set of “synonymous” codes
- *Formula* E.g., BMI
- *Transformation* E.g., “inpatient stay”
- *Phenotype* E.g., “experienced MI”
- *Cohort Definition* Phenotype + Time



“Data Cleaning” as First-Ranked Activity



“Data Cleaning” as First-Ranked Activity



Reporting RWE Best Practice

Structured Template and Reporting Tool for Real World Evidence (STaRT-RWE)

Table 1. Administrative Information

Table 2. Version History

Figure 1. Design Diagram

Table 3. Summary of Analytic Study Population

A. Meta-data about data source and software

B. Index Date (day 0) defining criterion

C. Inclusion Criteria

D. Exclusion Criteria

E. Predefined Covariates

F. Empirically Defined Covariates

G. Outcome

H. Follow up

Table 4. Analysis Specification

Table 5. Sensitivity Analyses

Table 6. Attrition Table

Table 7. Power and Sample Size Calculation

Table 8. Glossary of Terminology

Table 9. Abbreviations

Also

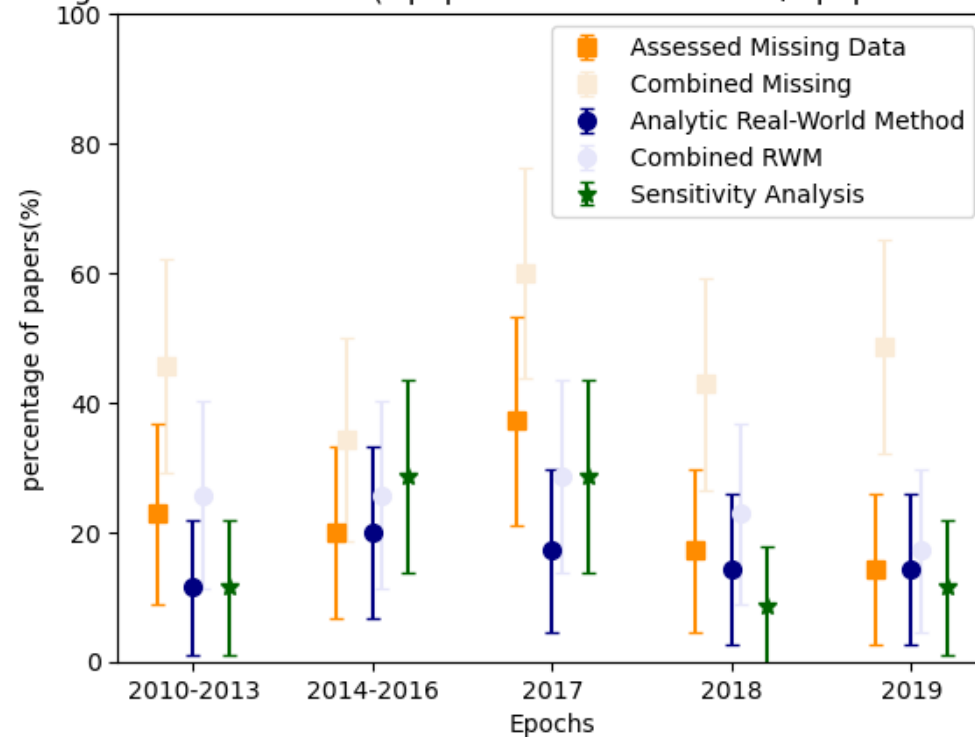
STROBE

RECORD

(see [equator-network](#))

Poor State of EHR-Based Research

Percentage of Methods Used (#papers used the methods/#papers included*100%)



“The papers that addressed all 3 phases of of analysis numbered 5 (2.9%).”

Li C, Alsheikh AM, Robinson KR, Lehmann HP. Use of Recommended Real-World Methods for Electronic Health Record Data Analysis Has Not Improved Over 10 Years. <https://www.medrxiv.org/content/10.1101/2023.06.21.23291706v1>.

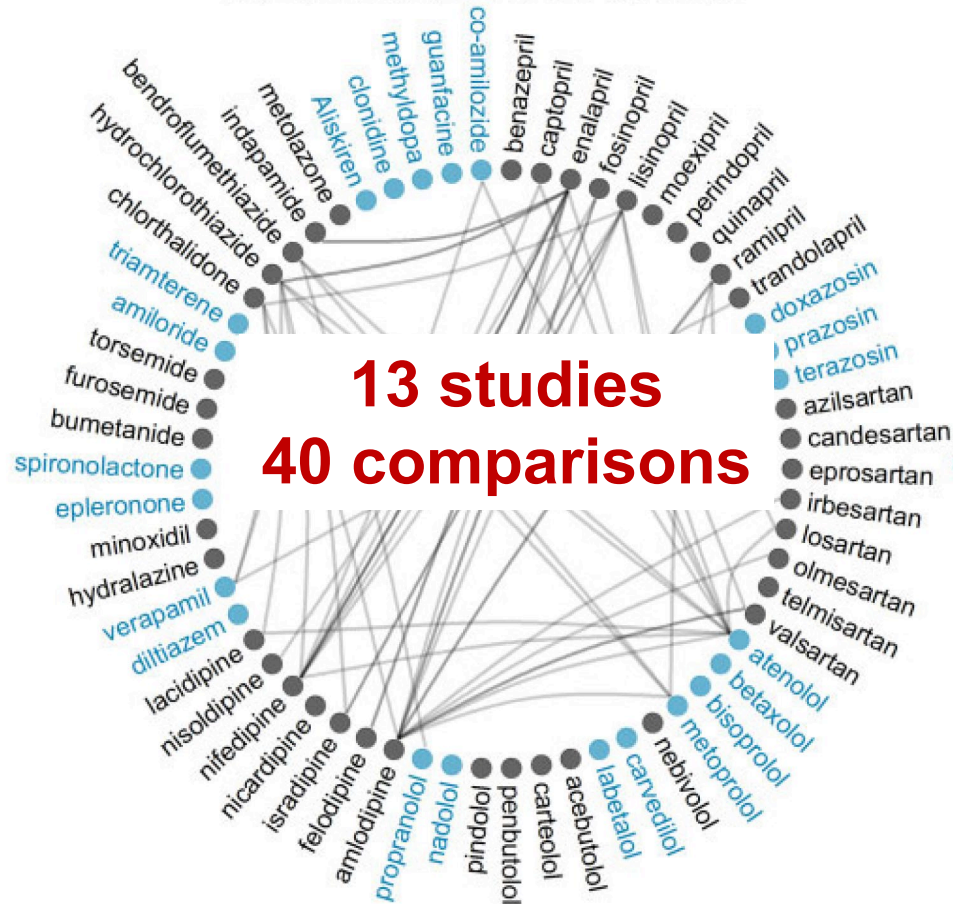
Examples from National Efforts

- PCORnet
 - 10 years, 9 Networks, > 800 Studies
- OHDSI
 - 14 years, > 200 Networks, > 575 Studies
- N3C
 - 3 years, > 70 sites (networks), >170 studies



Traditional Systematic Review

Randomized controlled trials



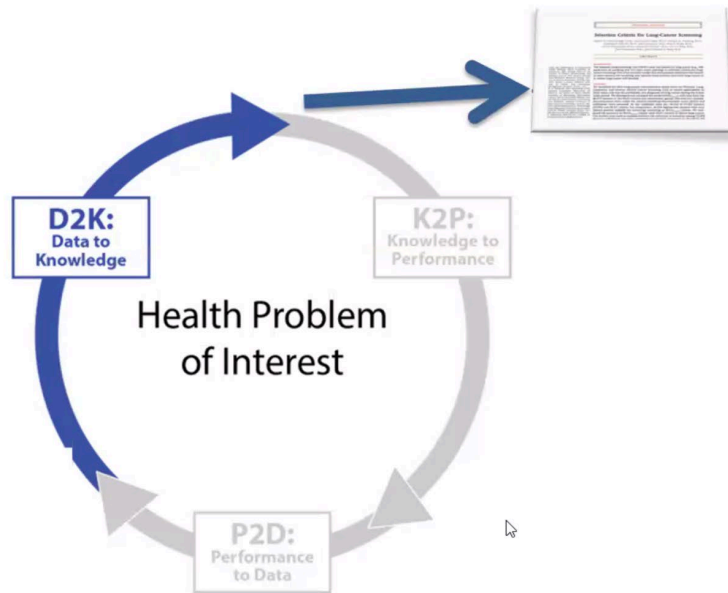
\$325,000/comparison

Source: Schuemie MJ, et al. Large-scale evidence generation and evaluation across a network of databases (LEGEND): assessing validity using hypertension as a case study. J Am Med Inform Assoc. 2020 Aug 1;27(8):1268-1277. Erratum in: J Am Med Inform Assoc. 2021 Jan 15;28(1):196.

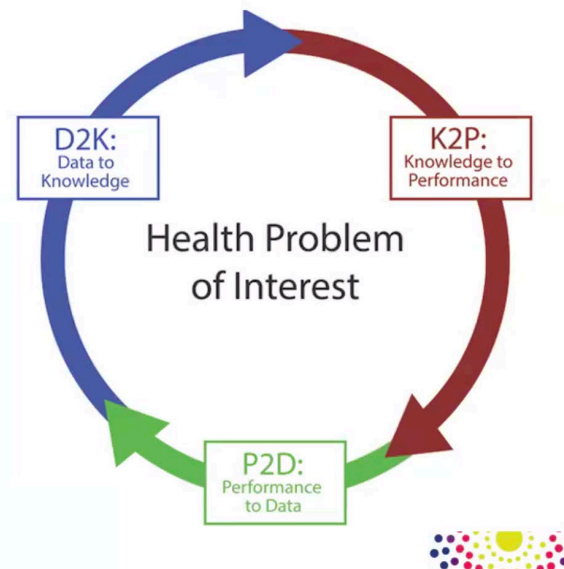
Communicating

The Challenge...

- How do we evolve this:



Into this?



FHIR:

*Fast Health
Interoperable Resources*

Currently: Clinical Data

Future: Evidence

EBMonFHIR

(Now: *HEvKA:*

Health Evidence

Knowledge Accelerator)

Open For Involvement!

FEvIR Platform

The FEvIR Platform includes many Builder Tools to create FHIR Resources without requiring expertise in FHIR or JSON, and Converter Tools to convert structured data to FHIR Resources.

My FEvIR Resources

View the resources that you made. Does not include resources initially created by other people.

View Resource List

View the entire list of available resources on the FEvIR Platform

Search

Search Resources on the FEvIR Platform

Builder Tools

Create New Resource

Add a title and resource type, or add JSON, to add a Resource to the FEvIR Platform

Project Builder

Create a Project Resource with an intuitive form (no manual JSON coding)

Citation Builder

Create a HL7[®] FHIR[®] Citation Resource with an intuitive form (no manual JSON coding)

CodeableConcept Builder

Create HL7[®] FHIR[®] JSON data element value for a CodeableConcept DataType

Converter & Importer Tools

MEDLINE Citation Converter

Enter a PMID to automatically create a HL7[®] FHIR[®] Citation Resource [Release Notes](#)

ClinicalTrials.gov Converter

Enter an NCT Identifier to automatically create HL7[®] FHIR[®] Resources [Release Notes](#)

MAGIC to FEvIR Converter

Select a MAGIC file (demo) to automatically create a HL7[®] FHIR[®] Resources [Release Notes](#)

RIS to FEvIR Converter

Submit a RIS file to automatically create a HL7[®] FHIR[®] Citation Resource [Release Notes](#)

SRDR+ Project Importer

Retrieve HL7[®] FHIR[®] Resources from Systematic Review Data Repository (SRDR+) [Release Notes](#)

CEDAR Search Importer

Retrieve Citation Resources from AHRQ CEPI Evidence Discovery and Retrieval (CEDAR) [Release Notes](#)

Specialized Tools

My Ballot

Vote on any open-for-voting terms in developing Code Systems [Release Notes](#)

Evidence Report Generator

Create a HL7[®] FHIR[®] Composition Resource (EvidenceReport Profile) by automatic generation from an Evidence Map. [Release Notes](#)

Recommendations Viewer (Demo)

View a selected set of recommendations in a table [Release Notes](#)

Knowledge Portal (Demo)

View an organized list of resources related to a Project [Release Notes](#)

Join the [Health Evidence Knowledge Accelerator \(HEvKA\)](#)

Active HEvKA Projects

[Apollo Accelerator Priority List](#)

[Bariatric Surgery Decision Example of FHIR Resources](#)

[Bariatric Surgery Decision Example of Implementation Tools](#)

[Evidence Based Medicine \(EBM\) Implementation Guide](#)

[Eligibility Criteria Matching Software Demonstration](#)

[Eligibility Criteria Matching Software Library](#)

[Eligibility Criteria specification with EvidenceVariable](#)

[Formula Building with KaTeX](#)

[GRADE Vocabulary Development Project](#)

[Measuring the Rate of Scientific Knowledge Transfer](#)

[ResearchOnFHIR: HL7 FHIR-based tools and initiatives to support clinical research](#)

[Scientific Evidence Code System \(SEVCO\)](#)

[View All Projects](#)

About [Fast Evidence Interoperability Resources \(FEvIR\) Platform](#)