OHDSI

OHDSI 2022 Tutorial:
An introductory journey from data to evidence

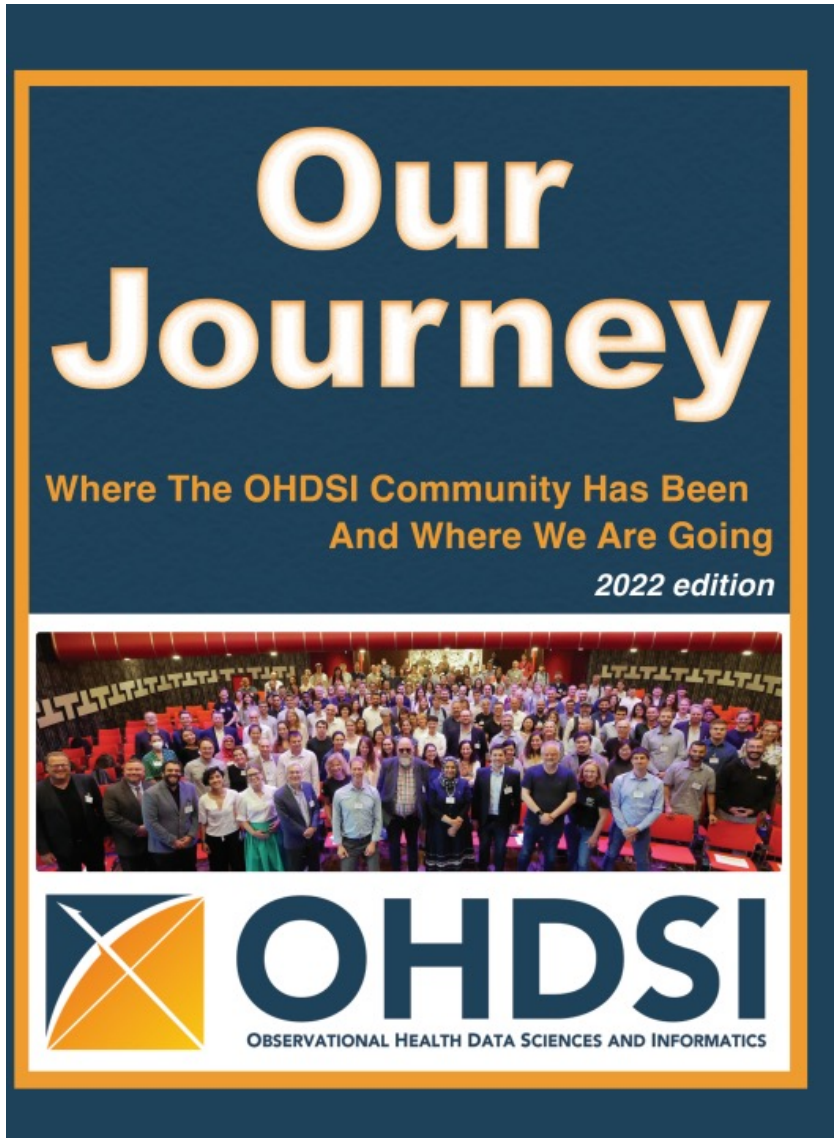
Welcome!

We thank the FDA for their generous support of the 2022 OHDSI symposium through the FDA SCIENTIFIC CONFERENCE GRANT PROGRAM (R13FD006972)

OHDSI's mission

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

OHDSI: Our Journey



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

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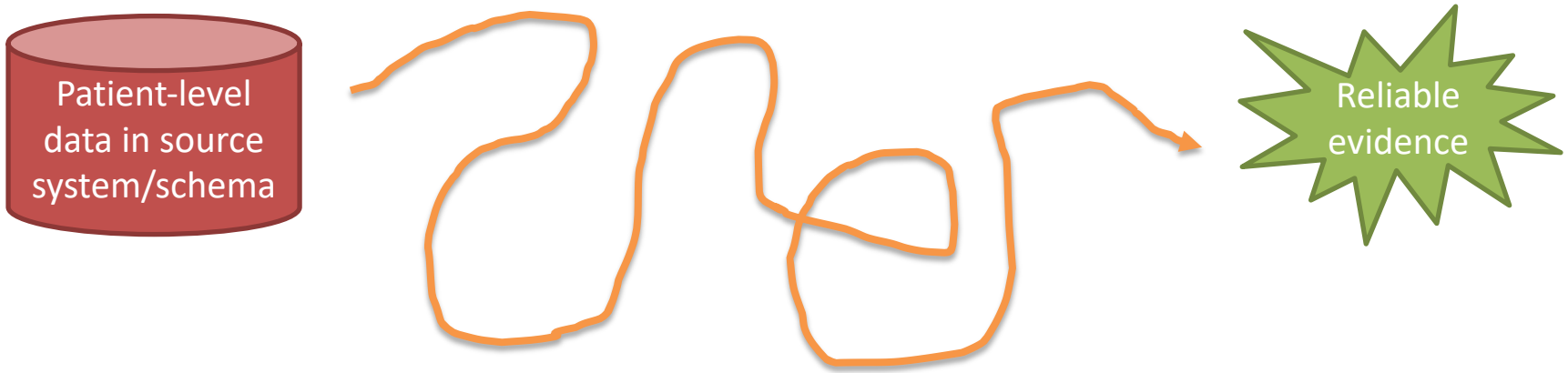
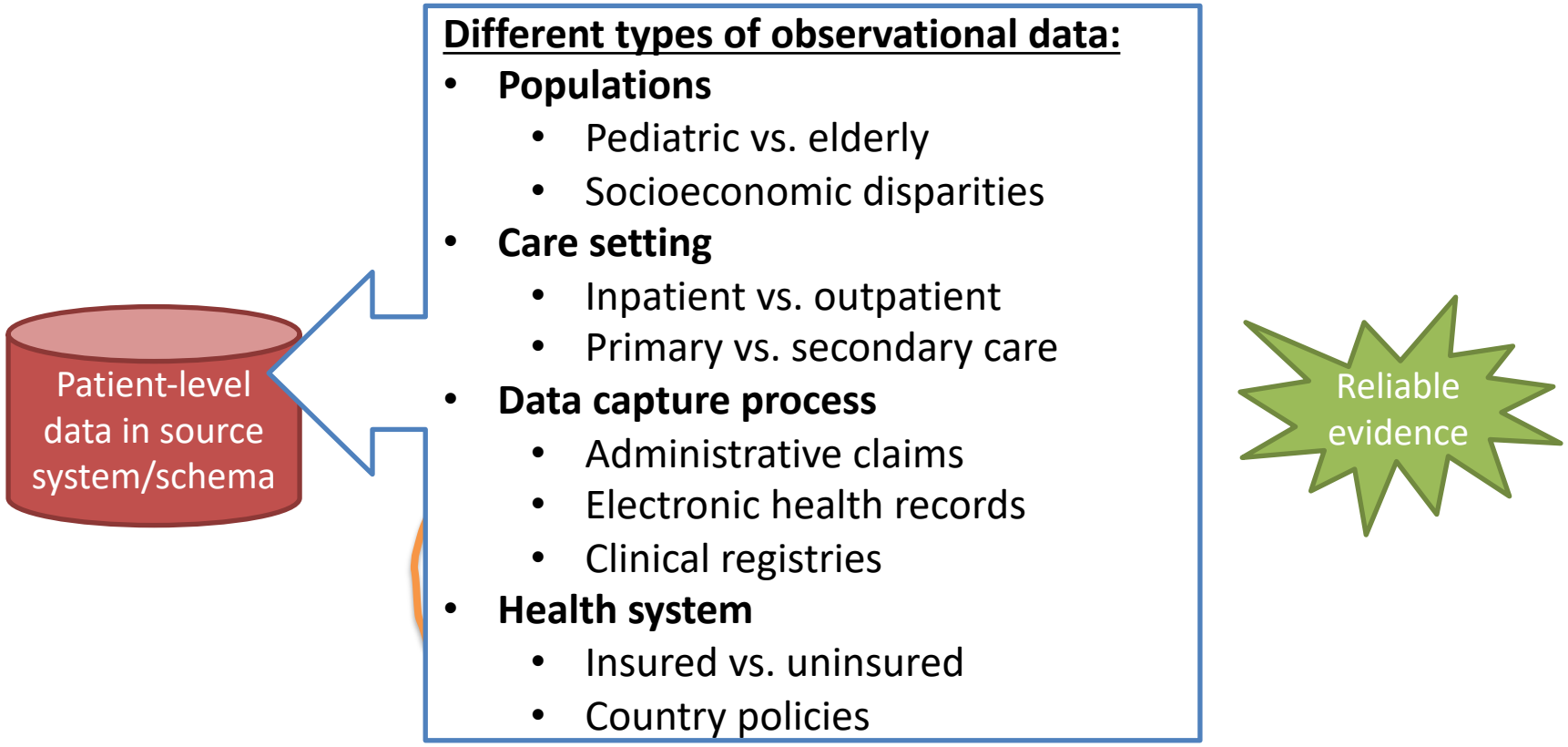


The journey to real-world evidence



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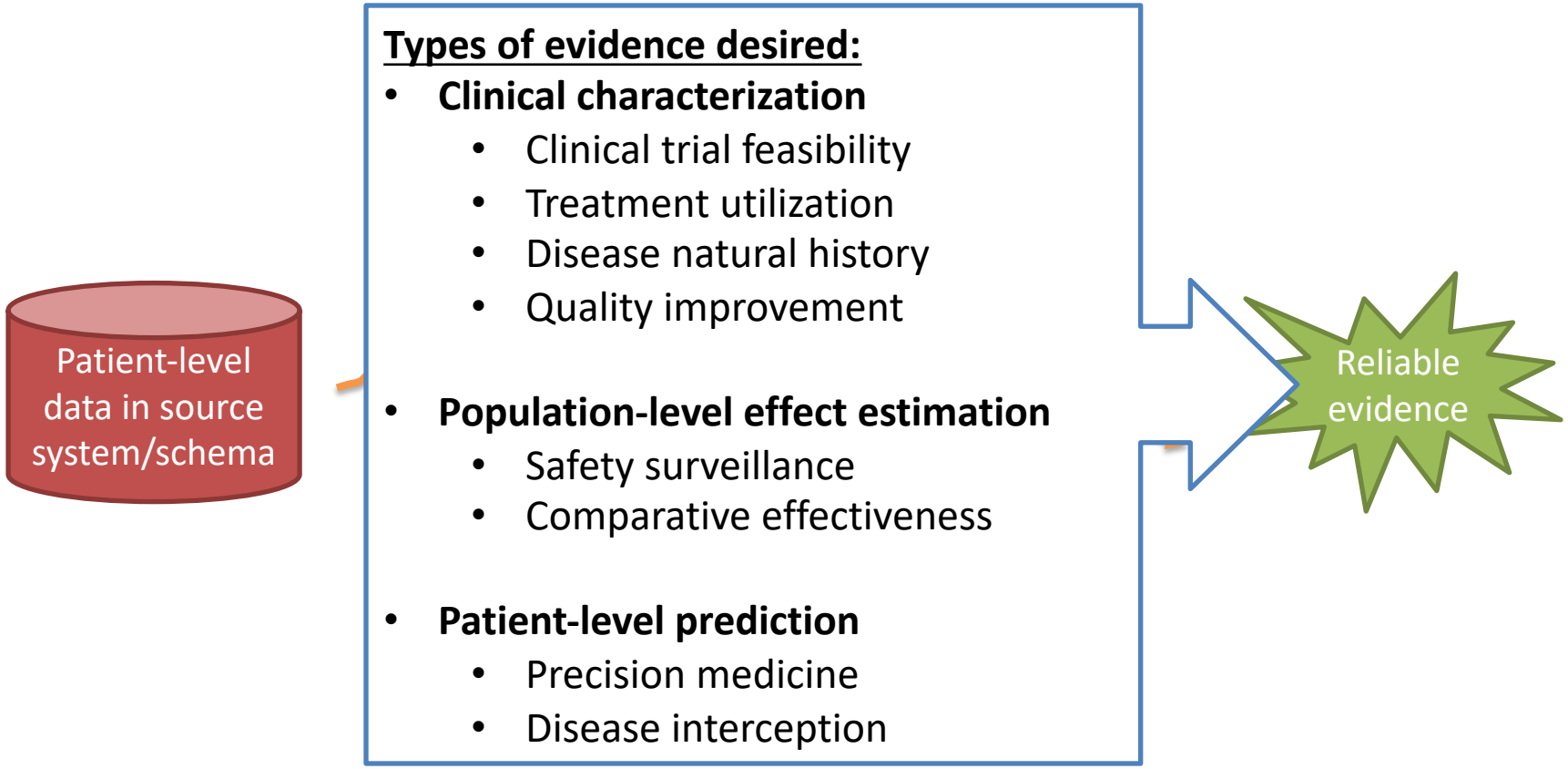
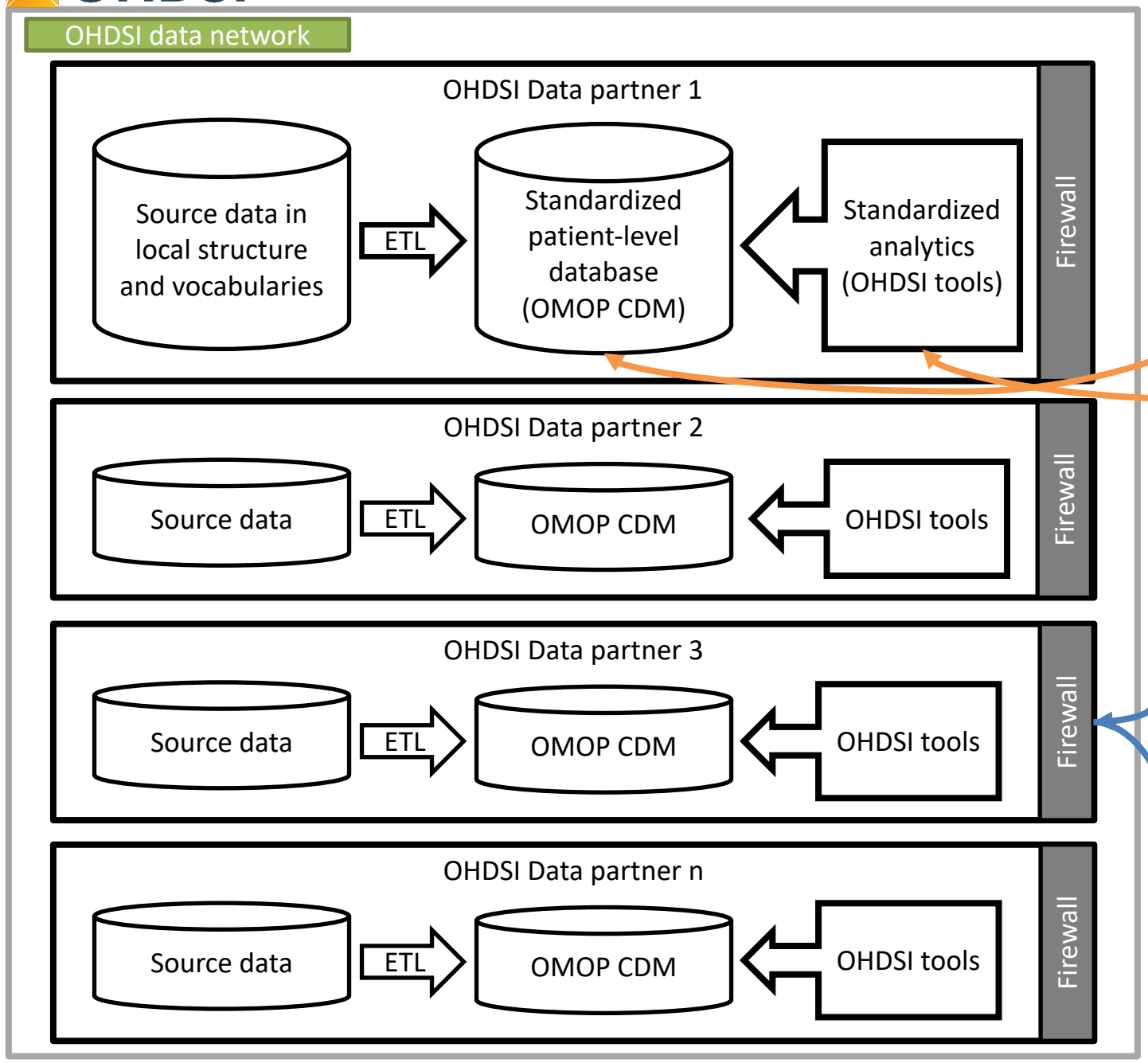


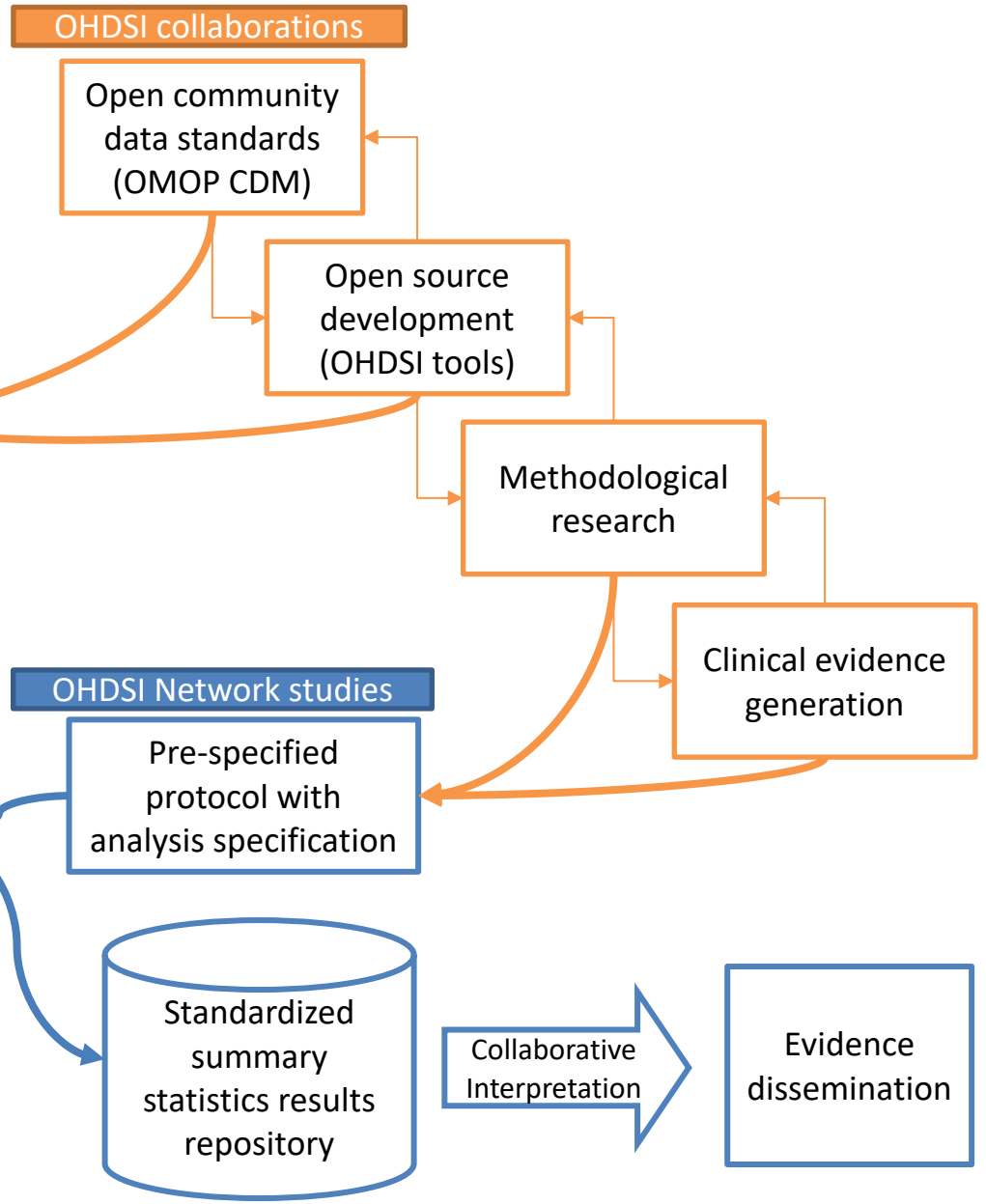
Full-day Tutorial – October 15
An Introductory Journey From Data To Evidence

Time	Title	Faculty
7:30 am - 8:30 am	Registration/Lite Breakfast (White Oak Foyer)	
8:30 am - 9:00 am	Overview of the OHDSI Journey: where are we going?	Patrick Ryan
9:00 am - 9:50 am	OMOP Common Data Model and vocabulary	Clair Blacketer
9:50 am - 10:00 am	Energy Break	
10:00 am - 10:50 am	ETL a source database into OMOP CDM	Melanie Philofsky
10:50 am - 11:00 am	Energy Break	
11:00 am - 11:50 am	Creating Cohort Definitions	Asieh Golozar
11:50 am - 12:30 pm	Buffet Lunch	
12:30 pm - 1:20 pm	Phenotype Evaluation	Gowtham Rao
1:20 pm - 1:30 pm	Energy Break	
1:30 pm - 2:20 pm	Characterization	Kristin Kostka
2:20 pm - 2:30 pm	Energy Break	
2:30 pm - 3:20 pm	Estimation	Martijn Schuemie
3:20 pm - 3:30 pm	Energy Break	
3:30 pm - 4:20 pm	Prediction	Jenna Reps
4:20 pm - 5:00 pm	Recap of the OHDSI Journey: Where do we go from here?	George Hripcsak

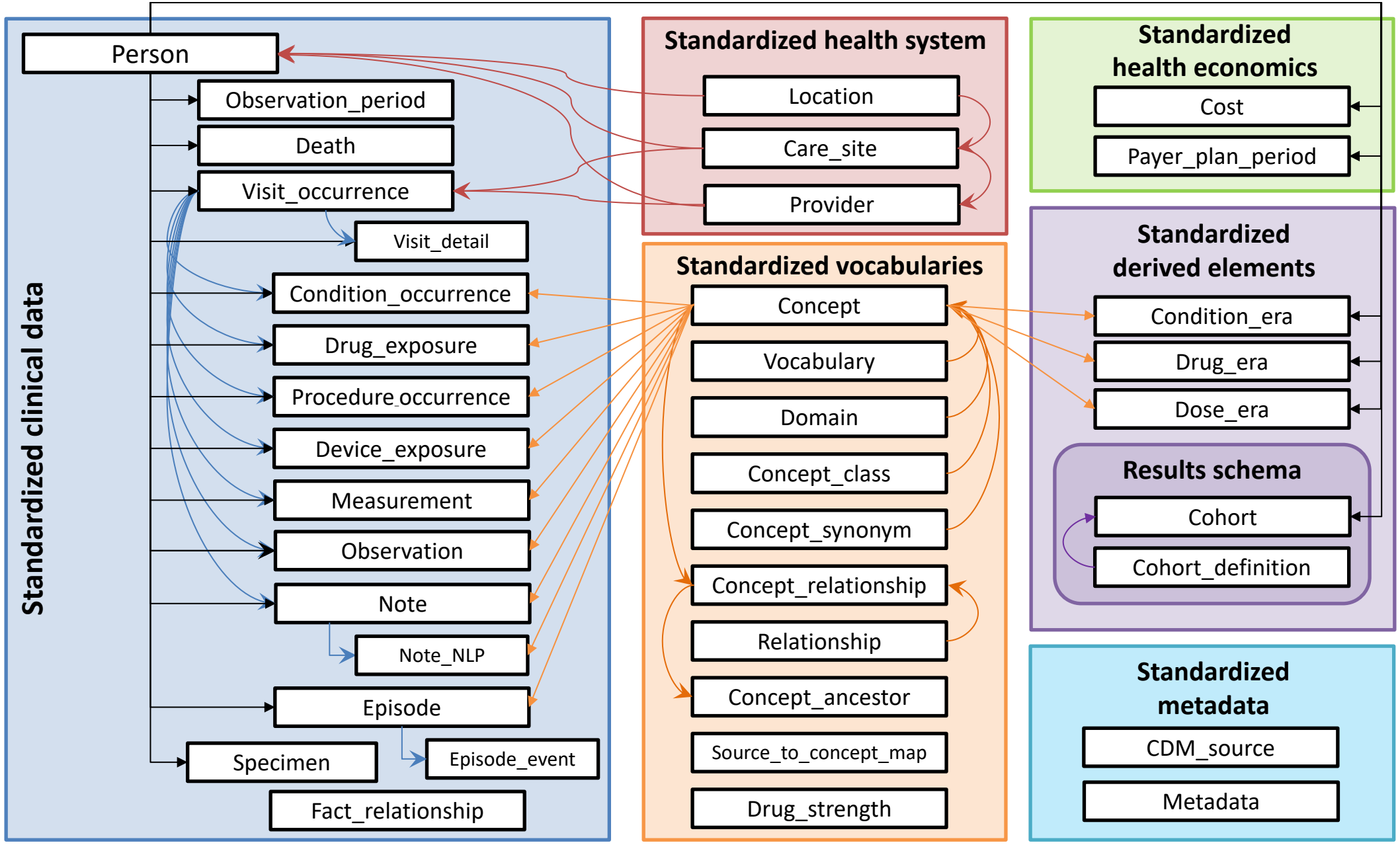
OHDSI

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





OMOP Common Data Model



HADES

Health Analytics Data-to-Evidence Suite

HADES (formally known as the OHDSI Methods Library) is a set of open source R packages for large scale analytics, including population characterization, population-level causal effect estimation, and patient-level prediction.

The packages offer R functions that together can be used to perform an observation study from data to estimates and supporting statistics, figures, and tables. The packages interact directly with observational data in the Common Data Model (CDM), and are designed to support both large datasets and large numbers of analyses (e.g. for testing many hypotheses including control hypotheses, and testing many analyses design variations). For this purpose, each Method package includes functions for specifying and subsequently executing multiple analyses efficiently. HADES supports best practices for use of observational data as learned from previous and ongoing research, such as transparency, reproducibility, as well as measuring of the operating characteristics of methods in a particular context and subsequent empirical calibration of estimates produced by the methods.

HADES has already been used in many published clinical and methodological studies, as can be seen in the Publications section.

Installation

See the Support section for instructions on setting up the R environment for HADES, including Java and RTools. Each package in HADES can be installed independently, but it is also possible to install all HADES packages at once, as described here. You can learn how connect to your database using HADES here.

Learn How to Use HADES

ZESTRIL- lisinopril tablet
Almatica Pharma LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ZESTRIL safely and effectively. See full prescribing information for ZESTRIL

ZESTRIL® (lisinopril) tablets, for oral use

Initial U.S. Approval: 1988

WARNING: FETAL TOXICITY

See full prescribing information for complete boxed warning.

- **When pregnancy is detected, discontinue Zestril as soon as possible. (5.1)**
- **Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus. (5.1)**

INDICATIONS AND USAGE

Zestril is an angiotensin converting enzyme (ACE) inhibitor indicated for:

- Treatment of hypertension in adults and pediatric patients 6 years of age and older (1.1)
- Adjunct therapy for heart failure (1.2)
- Treatment of Acute Myocardial Infarction (1.3)

Angioedema

Head and Neck Angioedema

Angioedema of the face, extremities, lips, tongue, glottis and/or larynx, including some fatal reactions, have occurred in patients treated with angiotensin converting enzyme inhibitors, including Zestril, at any time during treatment. Patients with involvement of the tongue, glottis or larynx are likely to experience airway obstruction, especially those with a history of airway surgery. Zestril should be promptly discontinued and appropriate therapy and monitoring should be provided until complete and sustained resolution of signs and symptoms of angioedema has occurred.

Patients with a history of angioedema unrelated to ACE inhibitor therapy may be at increased risk of angioedema while receiving an ACE inhibitor *[see Contraindications (4)]*. ACE inhibitors have been associated with a higher rate of angioedema in black than in non-black patients.

Intestinal Angioedema

Intestinal angioedema has occurred in patients treated with ACE inhibitors. These patients presented with abdominal pain (with or without nausea or vomiting); in some cases there was no prior history of facial angioedema and C-1 esterase levels were normal. In some cases, the angioedema was diagnosed by procedures including abdominal CT scan or ultrasound, or at surgery, and symptoms resolved after stopping the ACE inhibitor.

Comprehensive comparative effectiveness and safety of first-line antihypertensive drug classes: a systematic, multinational, large-scale analysis

Marc A Suchard, Martijn J Schuemie, Harlan M Krumholz, Seng Chan You, RuiJun Chen, Nicole Pratt, Christian G Reich, Jon Duke, David Madigan, George Hripcsak, Patrick B Ryan

Summary

Background Uncertainty remains about the optimal monotherapy for hypertension, with current guidelines recommending any primary agent among the first-line drug classes thiazide or thiazide-like diuretics, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, dihydropyridine calcium channel blockers, and non-dihydropyridine calcium channel blockers, in the absence of comorbid indications. Randomised trials have not further refined this choice.

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October 24, 2019
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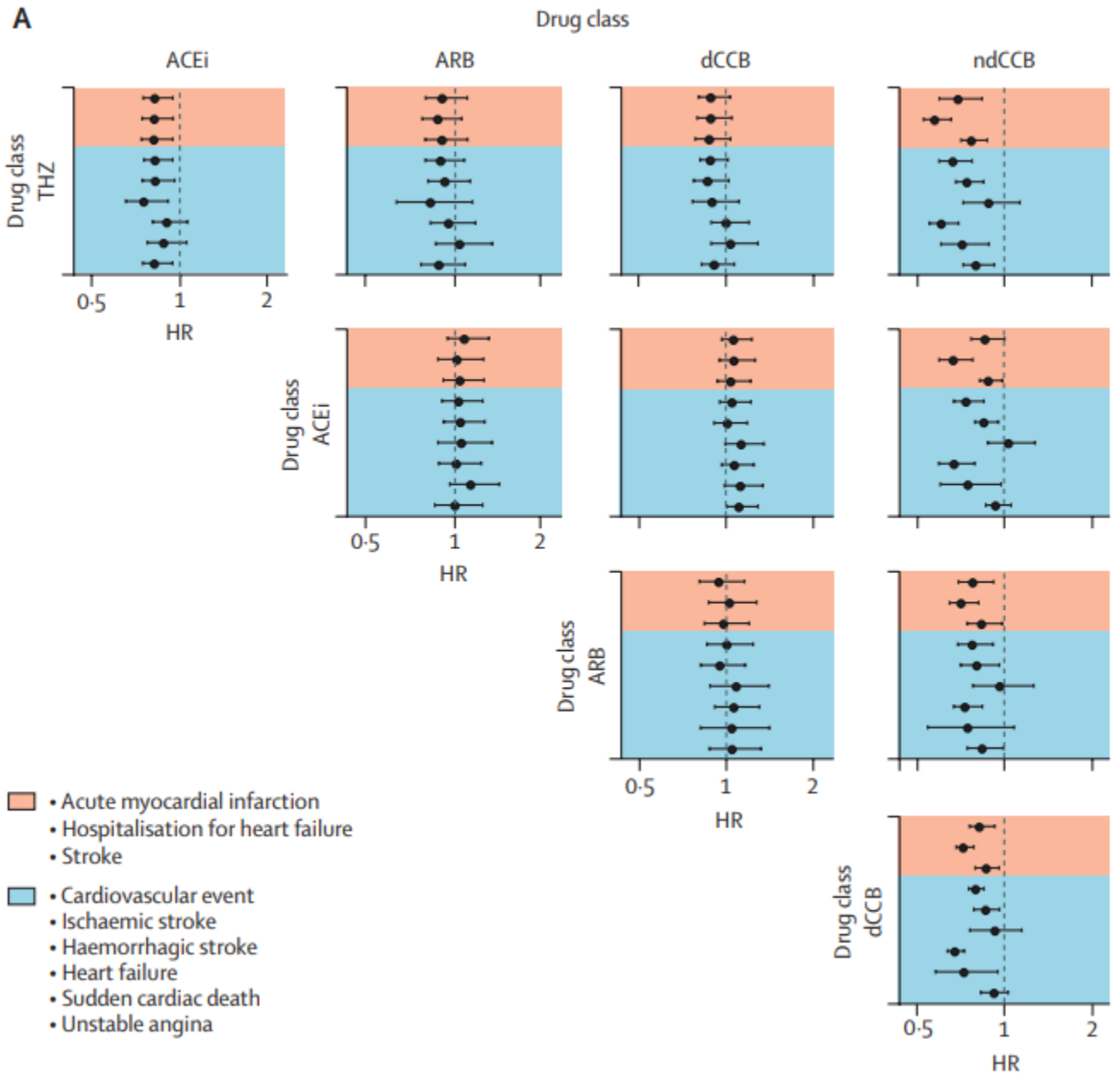
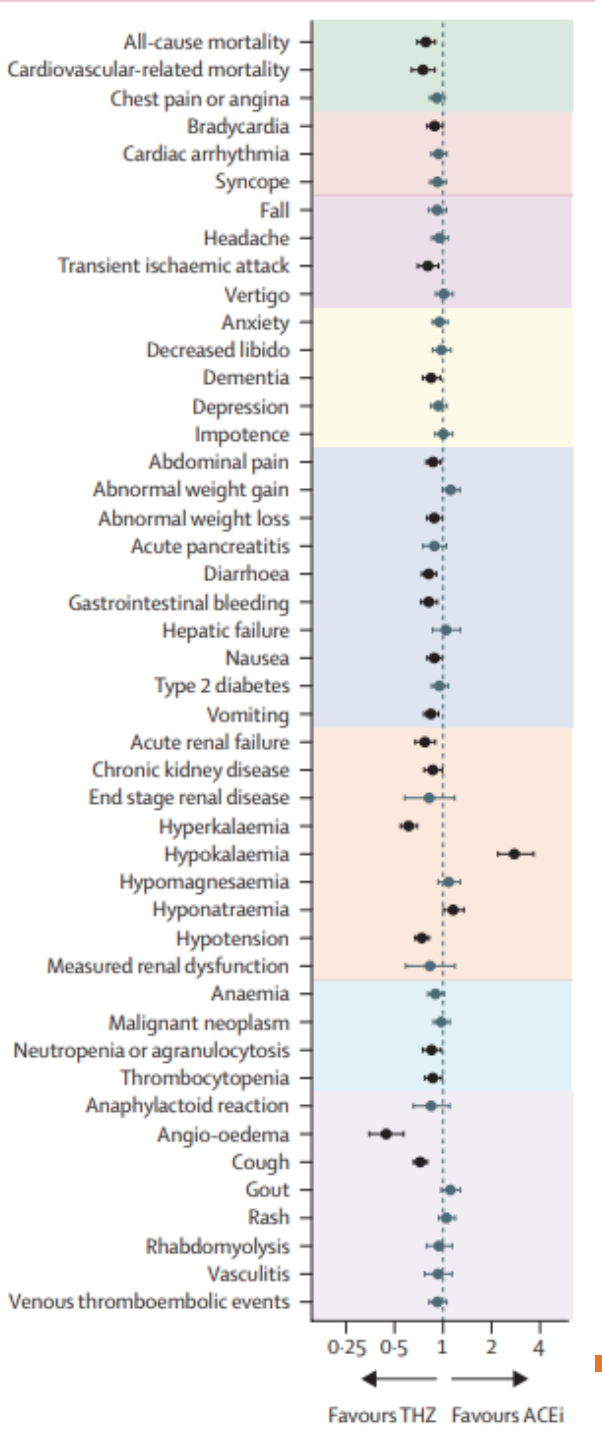
See Online/Comment
https://doi.org/10.1016/S0140-6736(19)32461-4


A
Drug class
ACEi
ARB
dCCB
ndCCB
Drug class THZ
Drug class ACEi
Drug class ARB
Drug class dCCB
0·5
1
2
HR
• Acute myocardial infarction
• Hospitalisation for heart failure
• Stroke
• Cardiovascular event
• Ischaemic stroke
• Haemorrhagic stroke
• Heart failure
• Sudden cardiac death
• Unstable angina


All-cause mortality
Cardiovascular-related mortality
Chest pain or angina
Bradycardia
Cardiac arrhythmia
Syncope
Fall
Headache
Transient ischaemic attack
Vertigo
Anxiety
Decreased libido
Dementia
Depression
Impotence
Abdominal pain
Abnormal weight gain
Abnormal weight loss
Acute pancreatitis
Diarrhoea
Gastrointestinal bleeding
Hepatic failure
Nausea
Type 2 diabetes
Vomiting
Acute renal failure
Chronic kidney disease
End stage renal disease
Hyperkalaemia
Hypokalaemia
Hypomagnesaemia
Hyponatraemia
Hypotension
Measured renal dysfunction
Anaemia
Malignant neoplasm
Neutropenia or agranulocytosis
Thrombocytopenia
Anaphylactoid reaction
Angio-oedema
Cough
Gout
Rash
Rhabdomyolysis
Vasculitis
Venous thromboembolic events
0·25
0·5
1
2
4
Favours THZ
Favours ACEi

Tutorial infrastructure

- Atlas http://tutorial5.us-east-1.elasticbeanstalk.com
- Jupyter http://jupyter.tutorial5.us-east-1.elasticbeanstalk.com
- RStudio http://rstudio.tutorial5.us-east-1.elasticbeanstalk.com

There are 170 RStudio user accounts: 'user1' - 'user170'. The password is 'Password1'