OBSERVATIONAL MEDICAL OUTCOMES PARTNERSHIP

OMOP Overview

Paul Stang, PhD

on behalf of the OMOP Research Team

FOUNDATION FOR THE National Institutes of Health

Observational Medical Outcomes Partnership

Public-Private Research Partnership established to inform the appropriate use of observational healthcare databases for studying the effects of medical products:

- Conducting methodological research to empirically evaluate the performance of alternative methods on their ability to identify true associations
- Developing tools and capabilities for transforming, characterizing, and analyzing disparate data sources across the health care delivery spectrum
- Establishing a shared resource so that the broader research community can collaboratively advance the science

Partnership Leadership

Research Investigators

The lead scientists for the OMOP project who guide and participate in the research across all project phases

Abraham G. Hartzema, PharmD, MSPH, PhD, FISPE
Professor and Eminent Scholar, Pharmaceutical Outcomes & Policy, Perry A. Foote Chair in Health Outcomes Research, University of Florida College of Pharmacy

David Madigan, PhD
Professor of Statistics, Columbia University

J. Marc Overhage, MD, PhD
Director, Medical Informatics and Research Scientist, Regenstrief Institute, Inc.; Regenstrief Professor of Medical Informatics, Indiana University School of Medicine, CEO; President of the Indiana Health Information Exchange

Judy Racoosin, MD, MPH
Sentinel Initiative Scientific Lead, US Food and Drug Administration

Patrick Ryan
Associate Director, Analytical Epidemiology, Johnson & Johnson Pharmaceutical Research and Development

Paul Stang, PhD
Senior Director, Epidemiology, Johnson & Johnson Pharmaceutical Research and Development

FNIH Management Team

FNIH provides program management, grants management, and operational support.

Executive Director
Thomas Scarnecchia
VP & CTO, Digital Aurora

Program Managers
Emily Welebob
Christian Reich

OMOP's Core Assets

Public-Private Partnership Governance Model
OMOP Research Lab and Community
OMOP Common Framework for Disparate Data Sources
Methods Library and Development Framework
Standard data characterization & ability to make comparisons across databases
Health Outcome of Interests

Governance

Executive Board Oversees Partnership Operations

- Janet Woodcock, MD - FDA
- Rebecca Burkholder -The National Consumers League
- Sherine Gabriel, MD, MSc - The Mayo Clinic
- Cynthia Gilman, JD - Henry Jackson Foundation
- Jesse L. Goodman, MD, MPH – FDA
- Stephen Jacobsen, MD, PhD - Southern California Permanente Medical Group
- Ronald L. Krall, MD - Retired GSK
- Richard Platt, MD, MSc - Harvard Medical School and Harvard Pilgrim Health Care
- Stephen Spielberg, MD, PhD - Children's Mercy Hospital
- Brian Strom, MD, MPH - Pennsylvania School of Medicine
- David Wheadon, MD - PhRMA
- Marcus Wilson, Pharm.D. - Healthcore

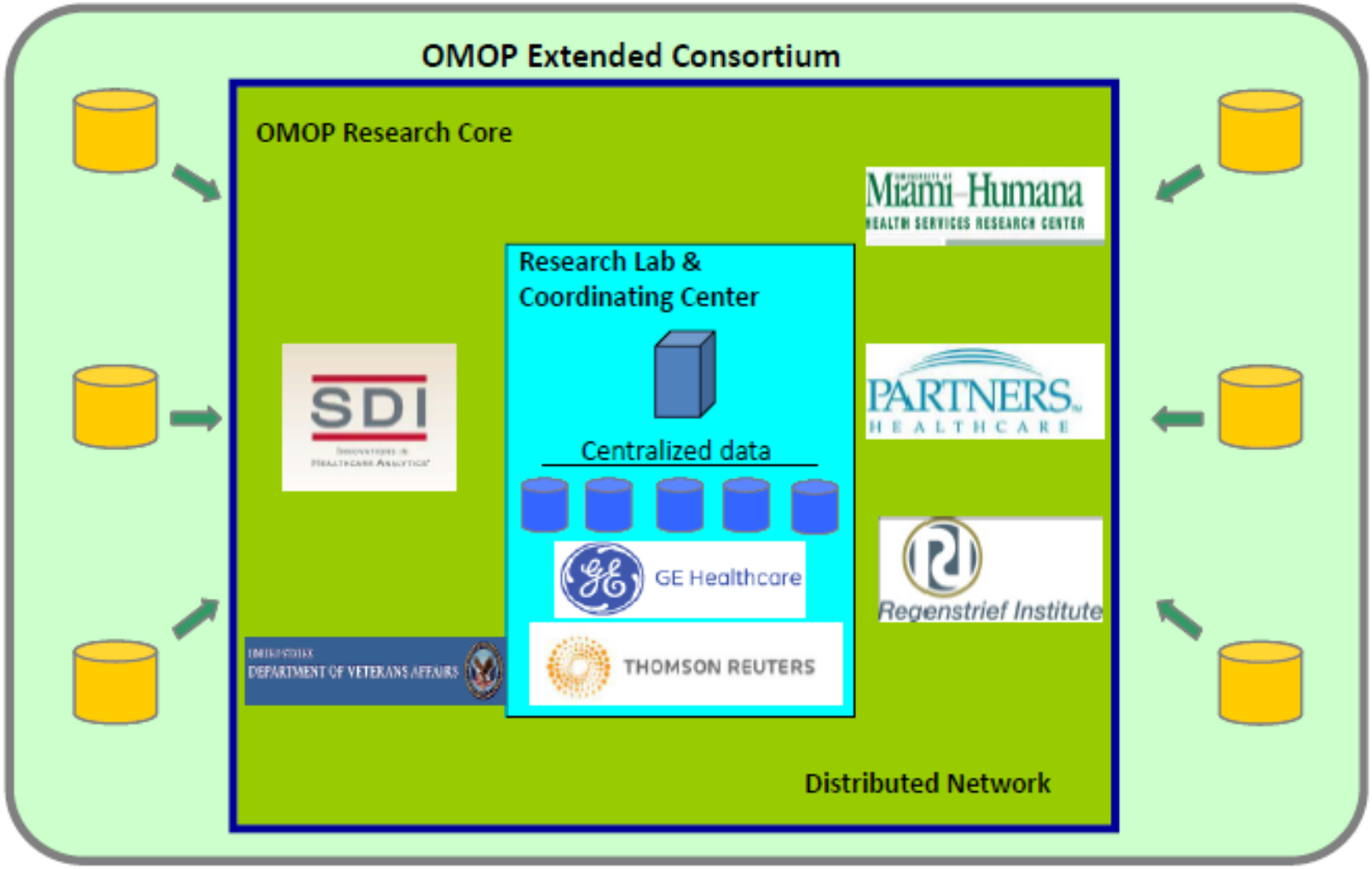
Scientific Advisory Board - independent review of and expert input into the scientific aspects of OMOP's activities

- Elizabeth Andrews, RTI Health Solutions
- Andrew Bate, Pfizer
- Jesse Berlin, Johnson & Johnson
- Robert Davis, Kaiser Permanente
- Steve Findlay, Consumer Union
- Sean Hennessy, University of Pennsylvania
- Mike Katz, FDA patient representative
- Allen Mitchell, Boston University
- David Page, University of Wisconsin
- Ken Rothman, RTI Health Solutions
- Judy Staffa, FDA

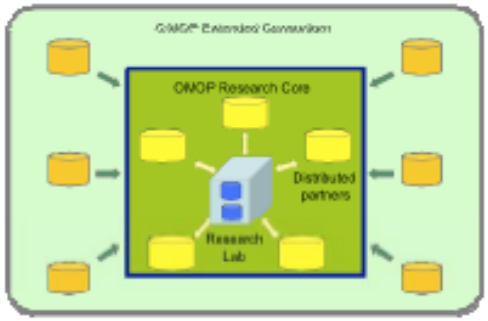
Healthcare Informatics Advisory Board - independent review and expert input into the technology, privacy, data model, and terminology

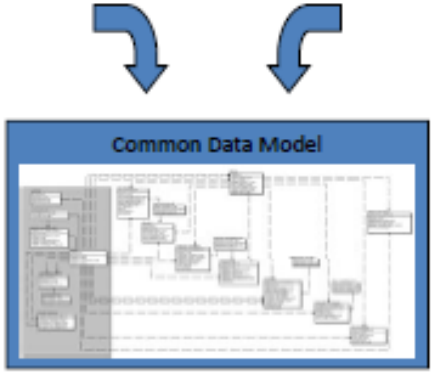
- Col. Kevin Abbott
- Jeff Brown, Harvard Medical School
- Stan Huff, Intermountain Healthcare
- Diane MacKinnon, IBM (retired)
- Ken Mandl, Harvard University
- Clem McDonald, National Library of Medicine
- Mitra Rocca, FDA
- Rob Thwaites, United BioSource Corporation

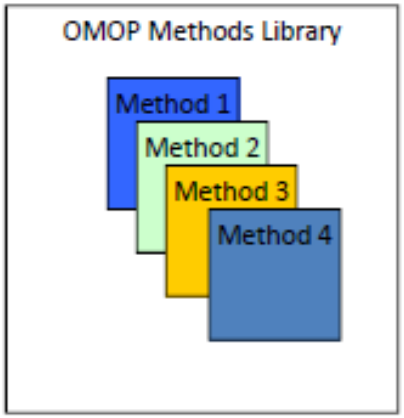
OMOP Data Community – First Two Years



OMOP research experiment workflow







Health Outcomes of Interest
- Angioedema
- Aplastic Anemia
- Acute Liver Injury
- Bleeding
- GI Ulcer Hospitalization
- Hip Fracture
- Hospitalization
- Myocardial Infarction
- Mortality after MI
- Renal Failure

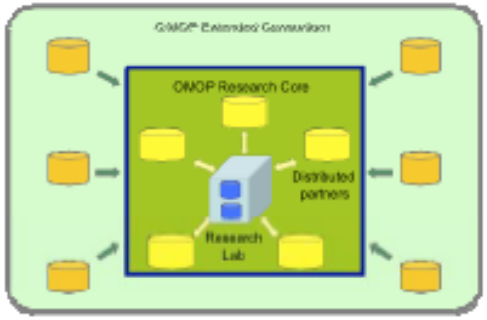
Drugs
- ACE Inhibitors
- Amphotericin B
- Antibiotics
- Antiepileptics
- Benzodiazepines
- Beta blockers
- Bisphosphonates
- Tricyclic antidepressants
- Typical antipsychotics
- Warfarin

Non-specified conditions

-All outcomes in condition terminology

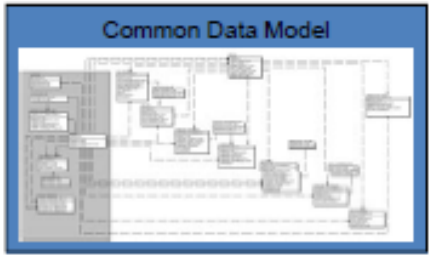
-'Labeled events' as reference
- -Warning
- -Precautions
- -Adverse Reactions
- -Postmarketing Experience

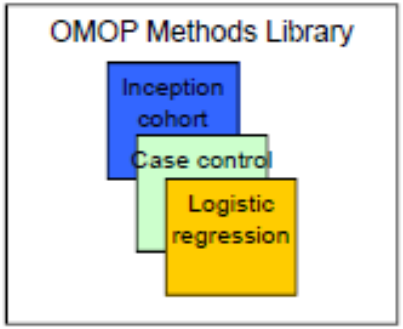
OMOP Research Experiment



- 10 data sources
- Claims and EHRs
- 200M+ lives
- Simulated data (OSIM)

- Open-source
- Standards-based
- OSCAR, NATHAN, GROUCH



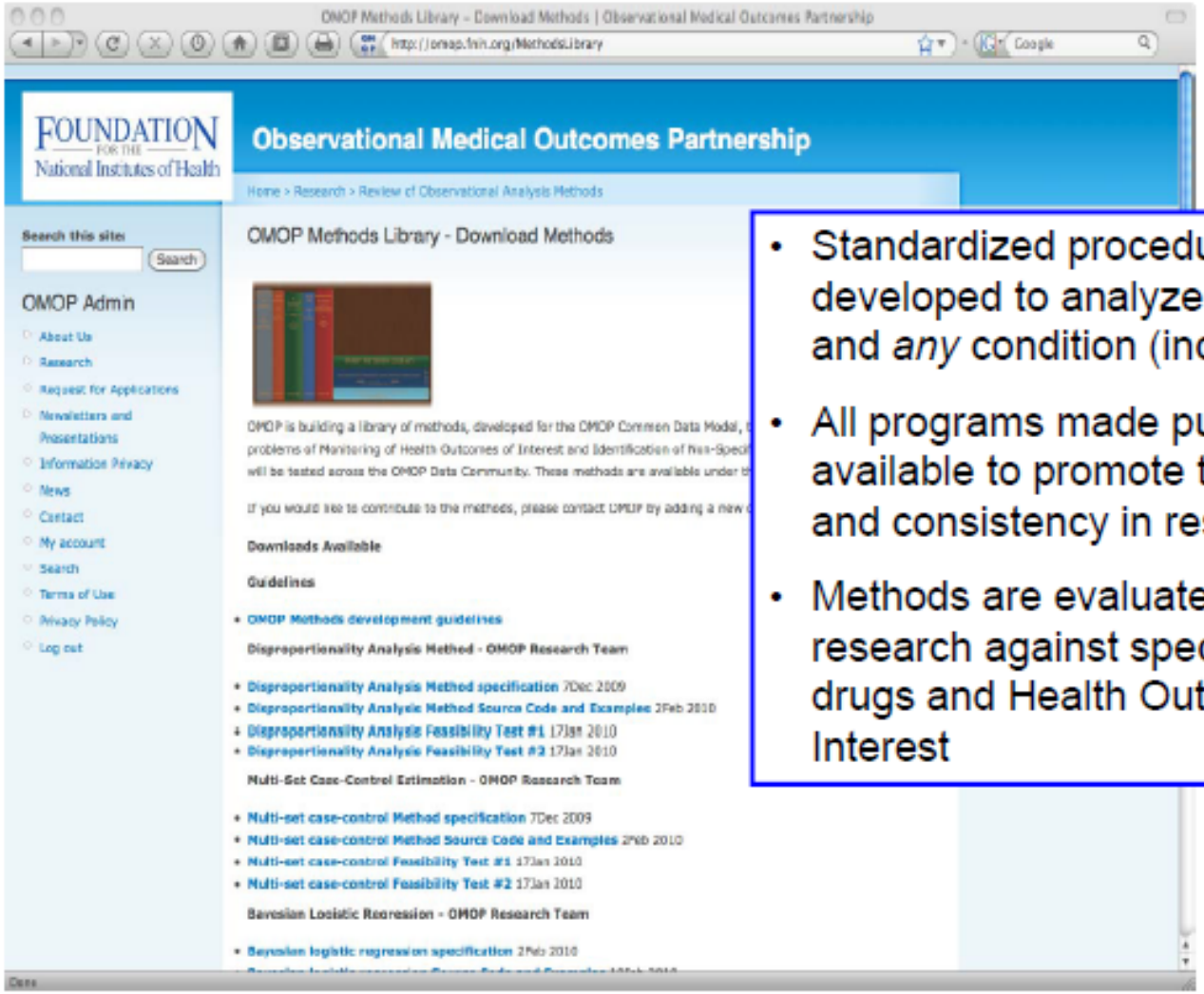


- 14 methods implemented as standardized procedures
- Full transparency with open-source code and documentation
- Epidemiology, statistical and machine learning designs

Drug

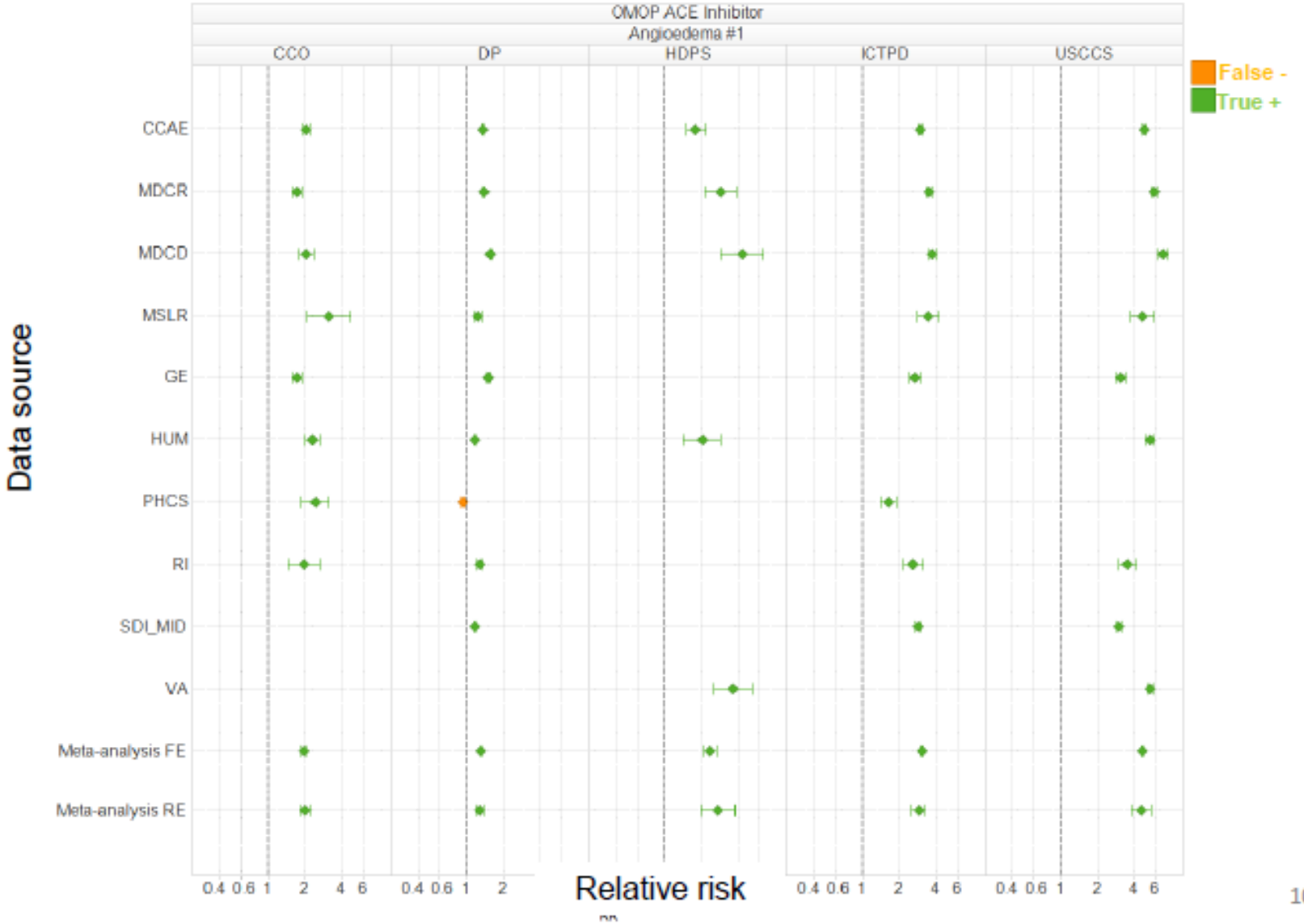
Outcome	ACE inhibitors	Amphotericin B	Antibiotics: erythromycins, sulfonamides, tetracyclines	Antiepileptics: carbamazepine, phenytoin	Benzodiazepines	Beta blockers	Bisphosphonates: alendronate	Tricyclic antidepressants	Typical antipsychotics	Warfarin
Angioedema										
Aplastic Anemia										
Acute Liver Injury										
Bleeding										
Hip Fracture										
Hospitalization										
Myocardial Infarction										
Mortality after MI										
Renal Failure										
GI Ulcer Hospitalization										

OMOP Methods Library for Implementation

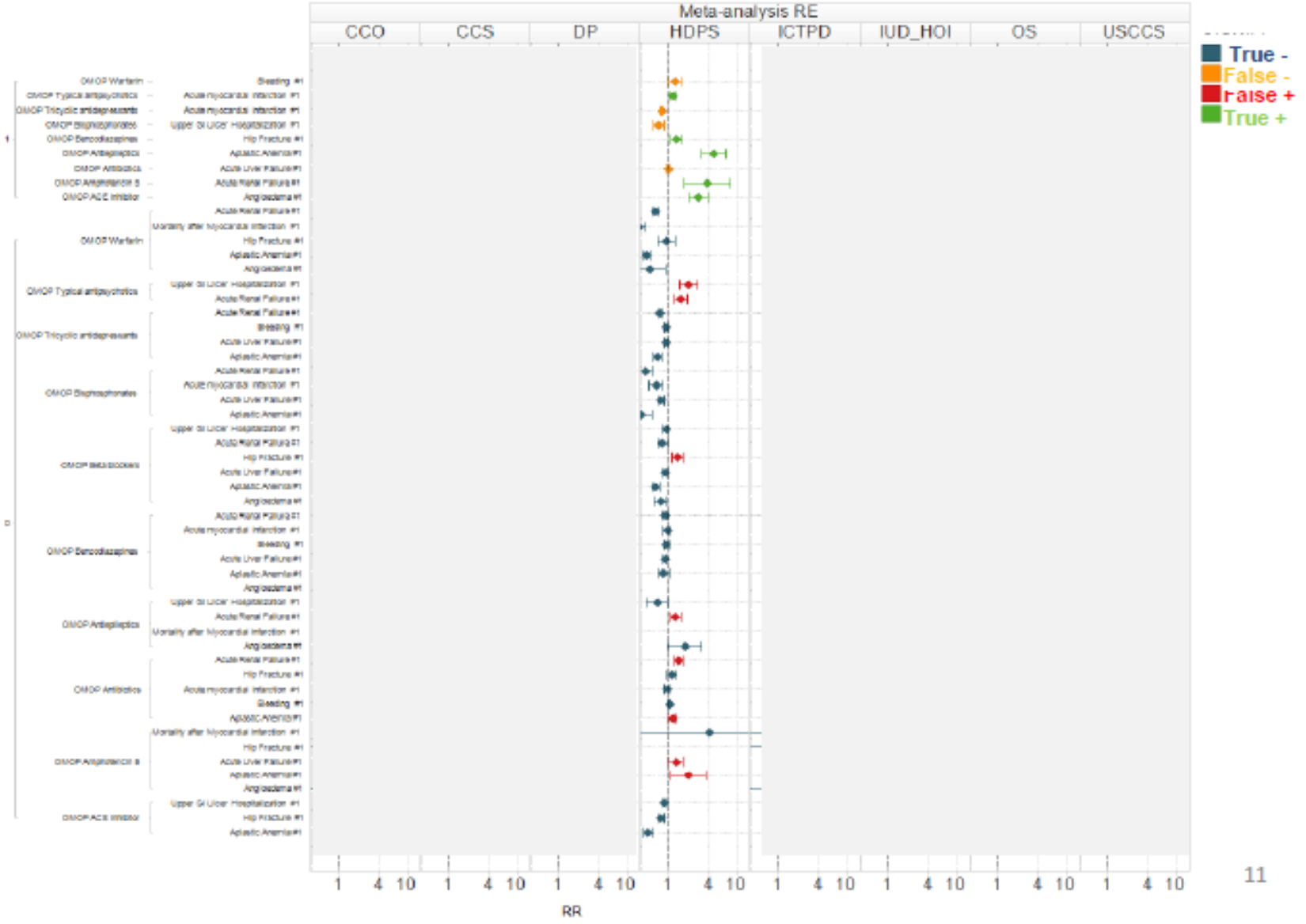


- Standardized procedures developed to analyze *any* drug and *any* condition (including HOIs)
- All programs made publicly available to promote transparency and consistency in research
- Methods are evaluated in OMOP research against specific test case drugs and Health Outcomes of Interest

Systematic Evaluation of the Effects of Medical Products



Establishing a System that Scales to a Broad Set of Questions

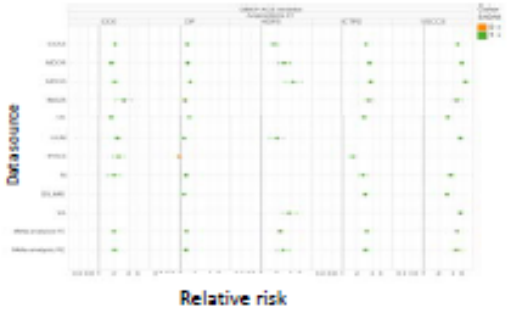


OBSERVATIONAL MEDICAL OUTCOMES PARTNERSHIP

Vision for a risk identification and analysis system 'causal dashboard'

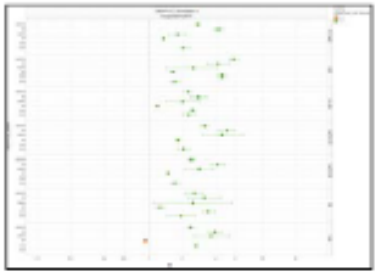
Drug Tricyclic antidepressants ▼ **Outcome** Acute myocardial infarction ▼

Strength of association

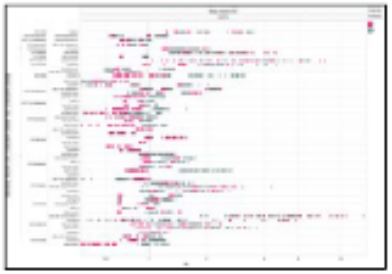


Consistency

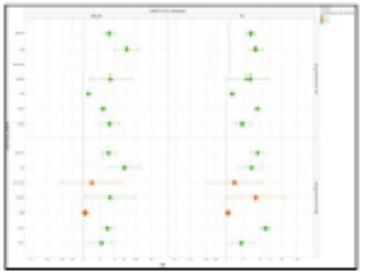
by data source



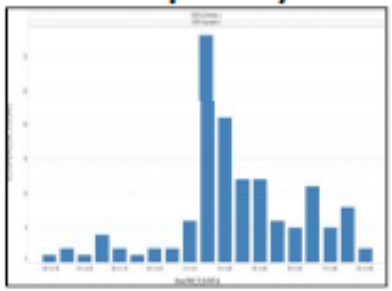
by method and parameters



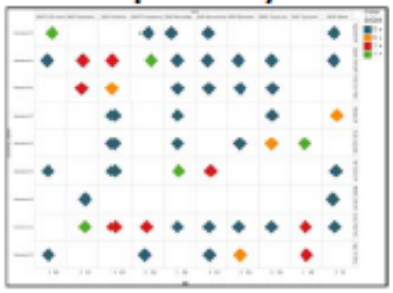
by outcome definition



Temporality

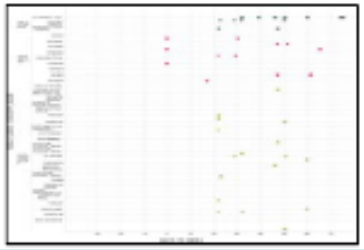


Specificity

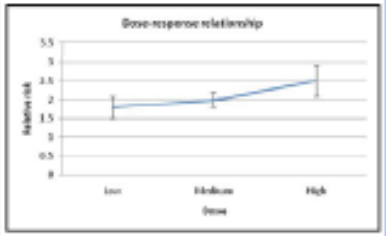


Plausibility

Interactive patient profiles



Biological gradient



Analogy

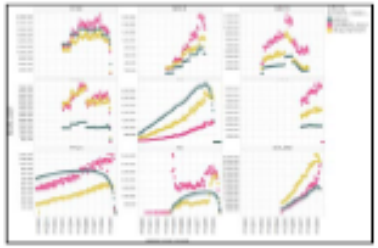
Explore related conditions and treatments

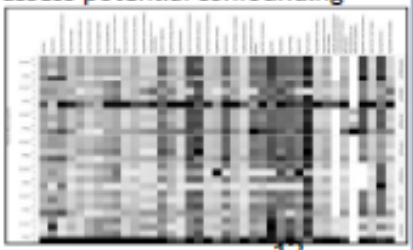
Experimental evidence

Dechallenge/Rechallenge

Coherence

Understand data and cohort to assess potential confounding





Ongoing Research Priorities

OMOP is pursuing the continuation of its mission to improve our ability for drug safety (and benefit) monitoring:

- **Advance methodological research** to explore the performance of methods over time, within specific populations of interest, and across a broader array of medical products and health outcomes
- **Refine and enhance OMOP's tools and capabilities** to translate research into practice
- **Sustain the shared resource (research lab)** so the research community maintains an open forum for collaborative research
- **Develop approaches to incorporating benefits** including increased application of clinical data to help ascertain benefits

In Summary

- Established public-private partnership and diverse research community
- Robust governance model with broad stakeholder representation across two advisory boards and an executive board
- Secure research computing laboratory and network of data partners with access to observational data representing over 200 million patients
- Stable framework for organizing, characterizing, and analyzing disparate data sources across a network of healthcare and insurance providers
- Process and expertise to define health outcomes of interest
- Process and technology to access the quality of a data source for use in observational research
- Growing portfolio (14) of tested and deployed analysis methods within the OMOP Research Lab and other data environments
- Open and transparent research culture
- Building open source community around the OMOP framework, technology, and methods