

# Observational Medical Outcomes Partnership and Mini-Sentinel Common Data Models and Analytics: A Systematic Data Driven Comparison

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OHSDI presentation 9/29/2015 Bram Hartzema & Brian Sauer



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# Disclosure

- Xiaofeng Zhou, Qing Liu, and Andrew Bate are employees and stockholders of Pfizer Inc.
- Yihua Xu, Brandon Suehs, Keran Moll, and Margaret Pasquale are employees of Comprehensive Health Insights, a wholly owned subsidiary of Humana. Brandon Suehs is a stockholder of Humana. Vinit Nair is an employee of Comprehensive Health Insights, and serves as the primary investigator from Humana for both the Observational Medical Outcomes Partnership and the Mini-Sentinel program.
- Abraham Hartzema, Michael Kahn, Brian Sauer, and Yola Moride received consulting fees and travel expenses in connection with providing input on the design of the study and interpretation of results.

# Background: CDM for Drug Safety Surveillance

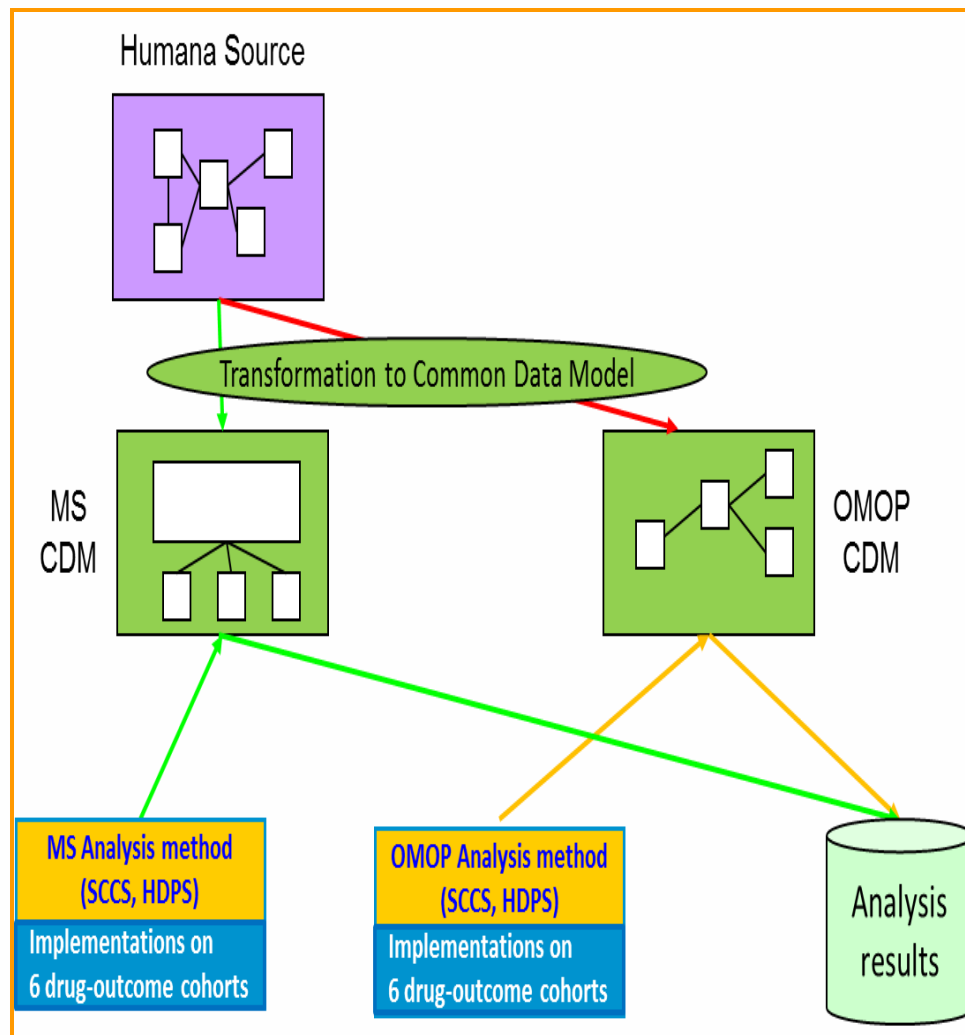
- ❑ A key component to coordinating surveillance activities across distributed networks is the design and implementation of a Common Data Model (CDM).
- ❑ CDM supports implementation of standardized analytics across organizations with different database structures.
- ❑ Observational Medical Outcome Partnership (OMOP) and FDA Mini-Sentinel (MS) CDMs have been proposed and widely used for Safety Surveillance activities, but no detailed comparison of the CDMs previously conducted

# Objective

- ❑ The overall objective of Humana-Pfizer CDM project is to evaluate OMOP and Mini-Sentinel CDMs from an ecosystem perspective to better understand how differences in CDMs and analytic tools affect usability and interpretation of results
  - Both CDMs have extensive purpose-built ecosystems of tools and programs for analytics capability and quality assurance

# Method

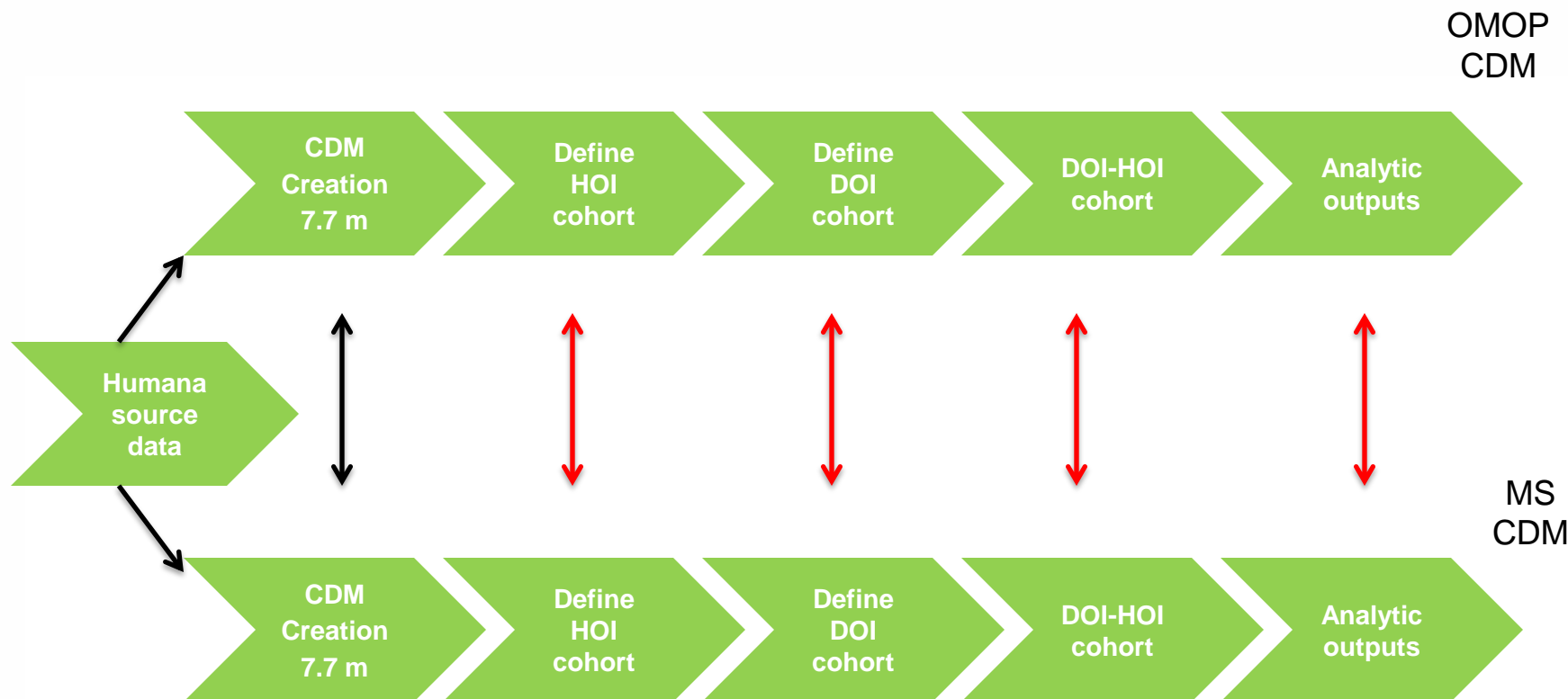
- ❑ Data Source: Humana claims data (2007 -2012)
- ❑ Data Mapping: Humana data to OMOP and MS CDMs
- ❑ Exposure and Outcome: six established positive drug-outcome pairs
- ❑ Analytic Methods:
  - High-dimensional propensity score (HDPS) based analytic procedure
  - Univariate self-controlled case series (SCCS) method
- ❑ Comparison:
  - Data at the patient level by source code and mapped concepts
  - Study cohort construction and effect estimates using two analytic methods



# Key Conceptual Difference

- OMOP
  - Standardized vocabularies
  - Data aggregation tables
  - Additional data elements
- Mini-Sentinel
  - Reflects concepts and granularity of source data
  - No standardized vocabulary
  - No secondary data aggregation tables

# Results: Differences in the Key Steps of the Dissection



Xu Y, Zhou X, Suehs BT, Hartzema AG, Kahn MG, Moride Y, Sauer BC, Liu Q, Moll K, Pasquale, MK, Nair VP, Bate A, "A comparative assessment of Observational Medical Outcomes Partnership and Mini-Sentinel common data models and analytics: implications for active drug safety surveillance", *Drug Saf* 2015 (June 9)

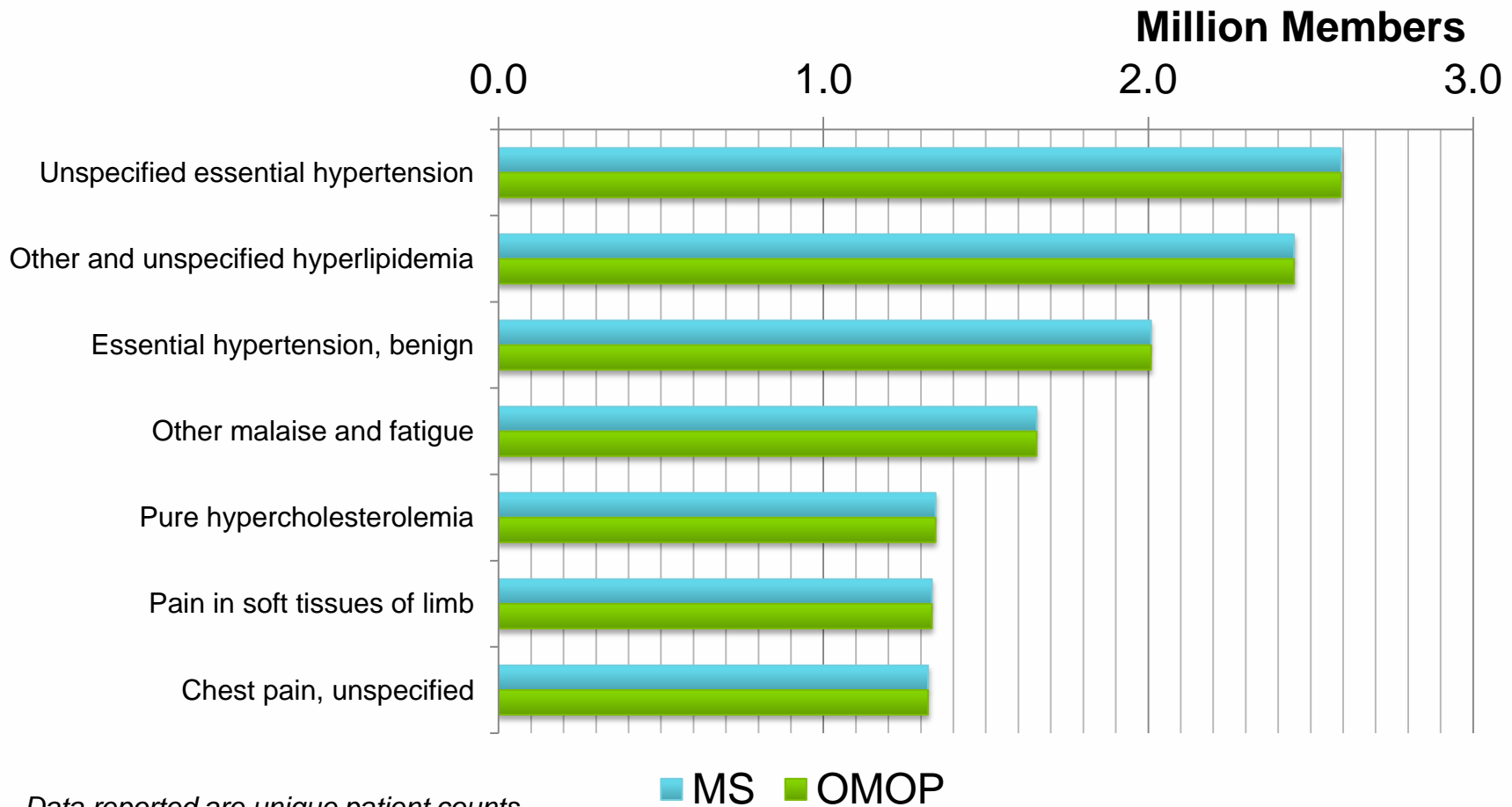


Steps where further discordance was introduced



Step with no or minimal discordance  
DOI – Drug of Interest  
HOI – Health Outcome of Interest

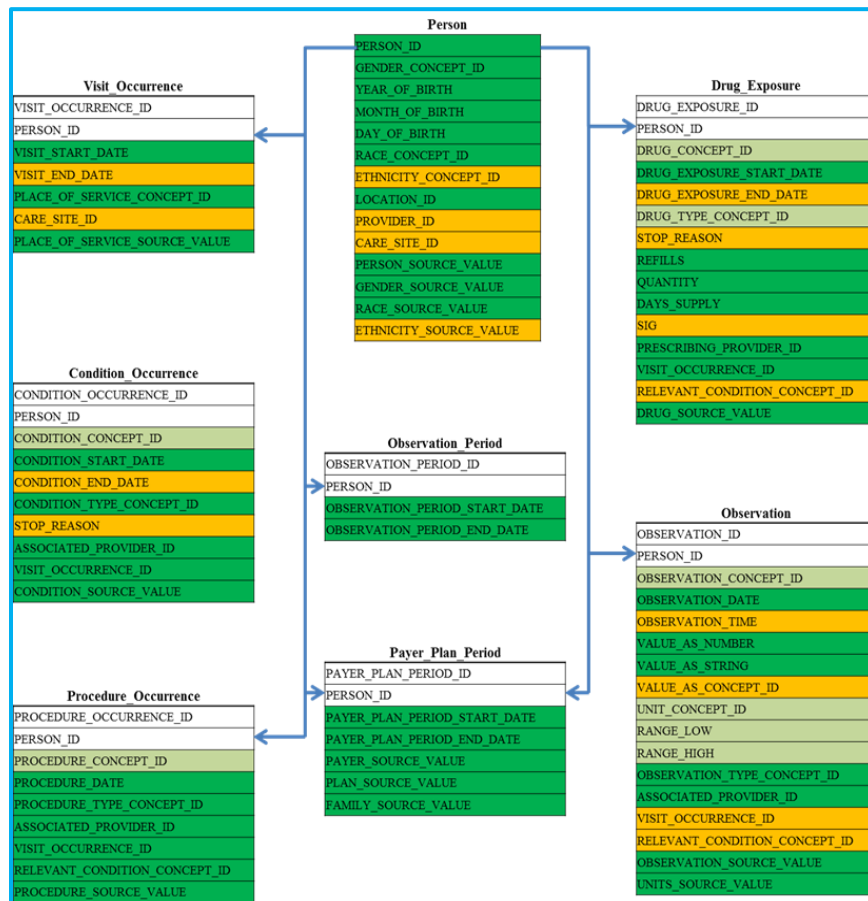
# Common Conditions/Diagnosis Codes – Source level



# Results: Conceptual Differences in Mapping

- ❑ No information loss when mapping source codes into MS CDM
- ❑ There was minimal information loss when source data were transformed into OMOP standard vocabulary
- ❑ Most unmapped codes in this study had no or minimal impact on the active surveillance method testing.

Database heat map: overall mapping quality of the Humana database in OMOP CDM



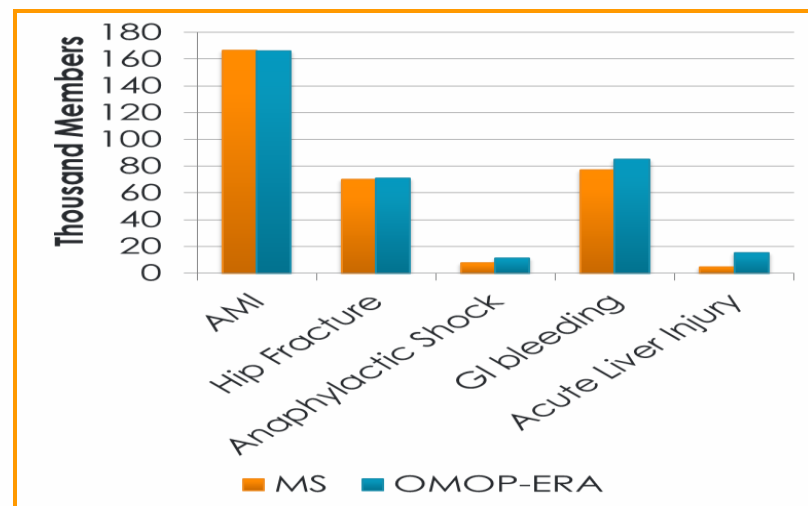
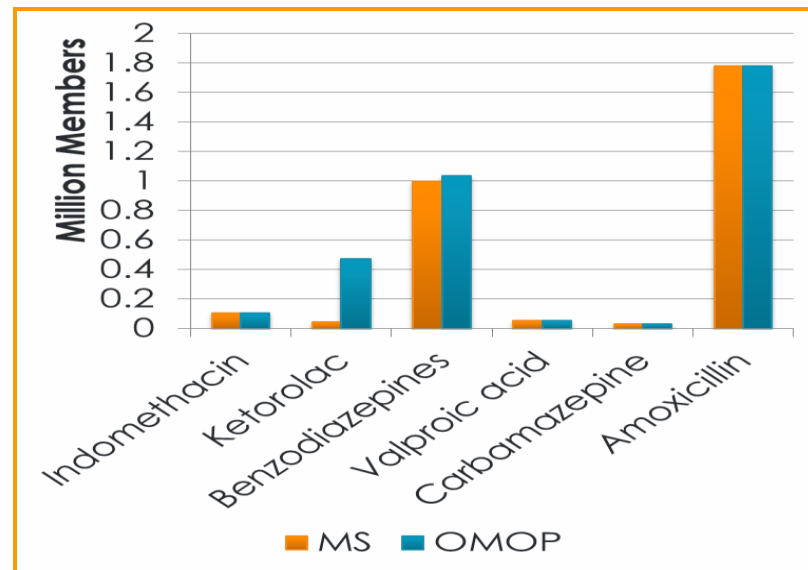
**Dark green, complete mapping; light green, incomplete mapping; yellow, not available to map; white, system generated.**

Note: Selected Humana OMOP CDM data tables used for this study were included in this figure.

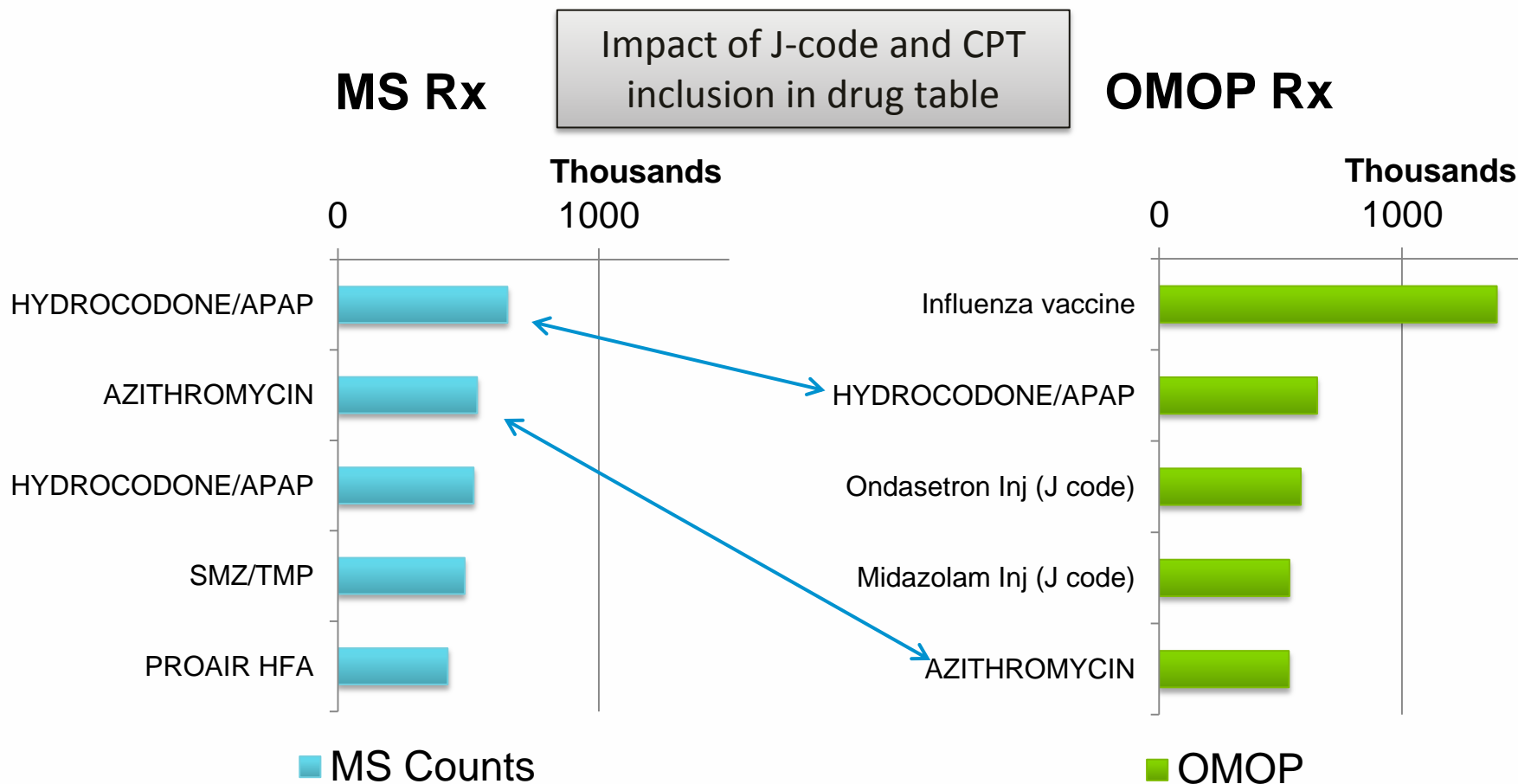


# Results: Conceptual Differences in Cohort Creation

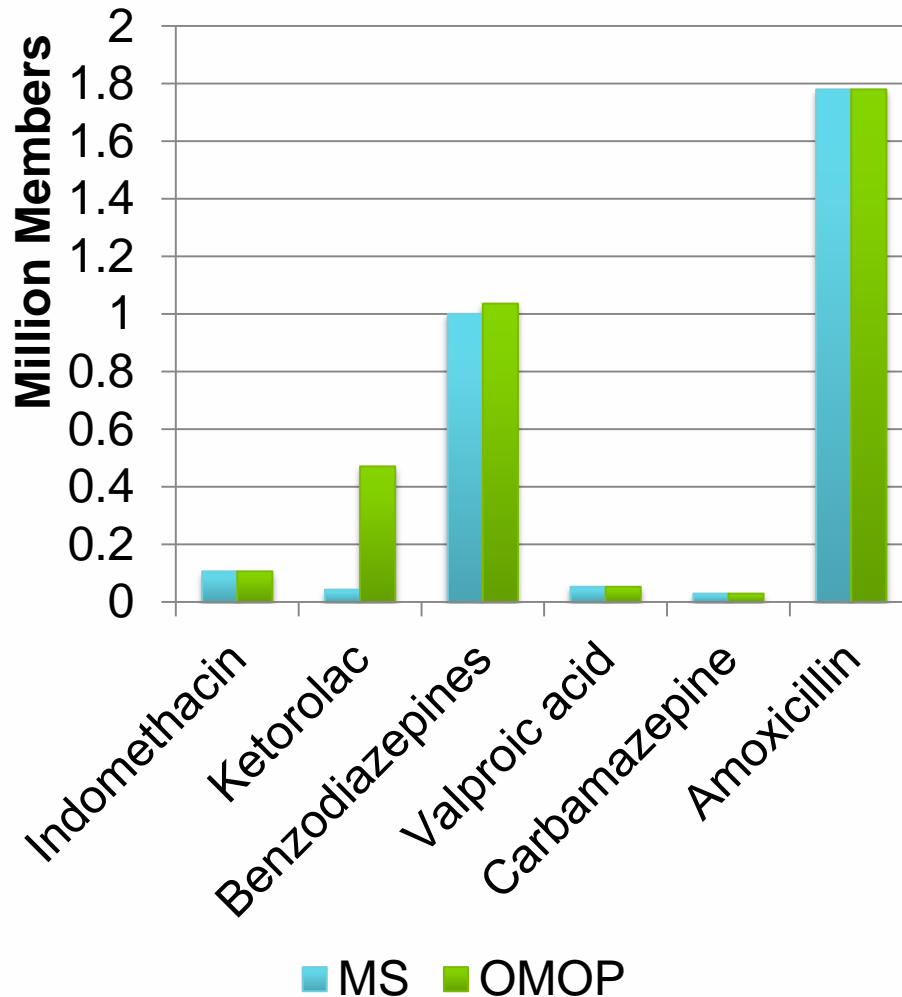
- ❑ Drug exposure table structure differs across two CDMs
- ❑ Large differences in three HOI and two DOI cohorts extracted from each CDM



# Rx Frequency – Source Level

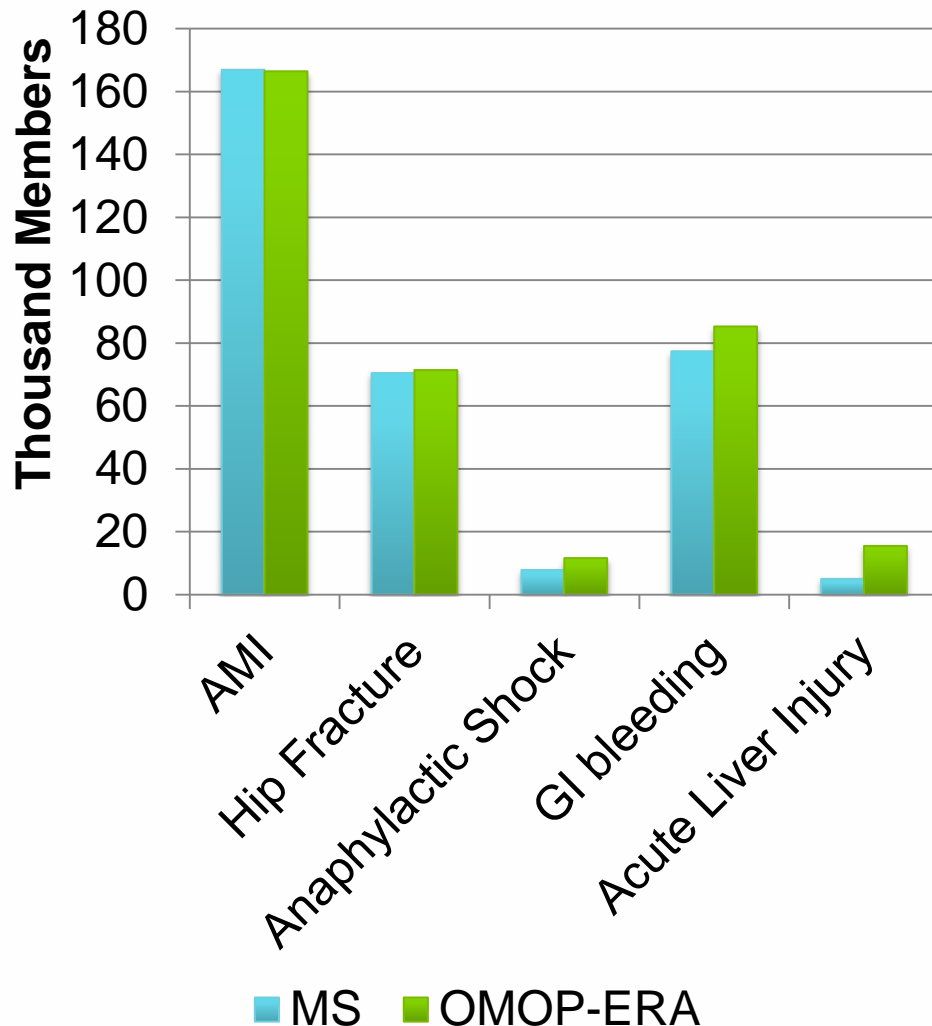


# DOI Cohorts



- Good agreement:
  - Indomethacin
  - Valproic acid
  - Carbamazepine
  - Amoxicillin
- Discordance:
  - Ketorolac
  - Benzodiazepine

# HOI Cohorts



- Good agreement:
  - AMI, Hip Fracture
- Discordance:
  - GI bleed, ALI, Anaphylaxis

# Potential Explanations for Findings

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3 primary factors that may contribute to differences observed in HOI & DOI cohorts:

- Mapping
- CDM structure
- Definitional differences



# Methods Testing

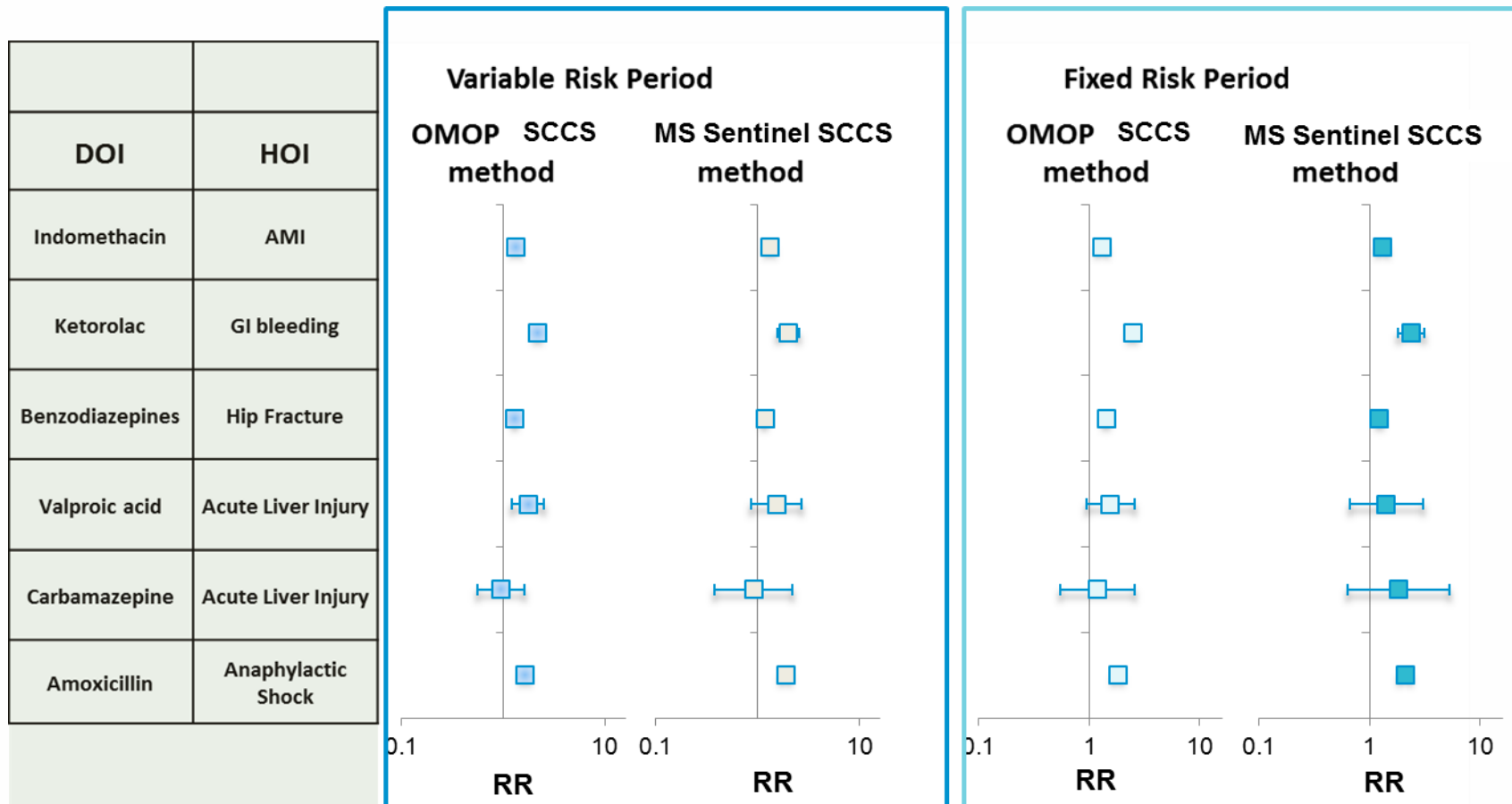
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- Why methods testing?
- HDPS and USCCS methods
- “Community-developed” code
- Key differences in method implementation
  - Cohort identification
  - Analysis



# Results: Testing SCCS Method

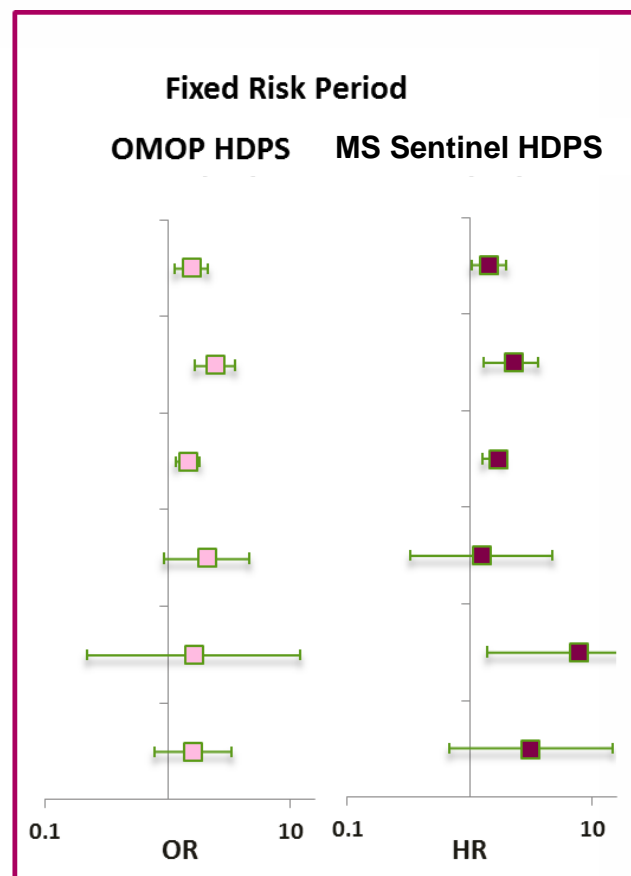
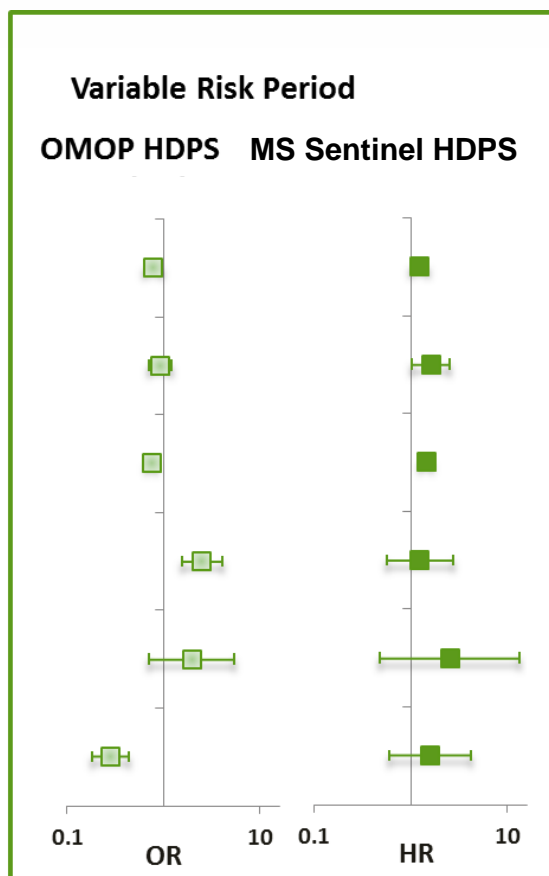
Key Finding: Conceptual differences at data model level had slight but not significant Impact on identifying the known safety associations



# Results: Testing HDPS Based Analytic Procedure

Key Finding: Differences at ecosystem level can lead to strikingly different risk estimation (primarily due to choice of analytic approach and its implementation)

DOI	HOI
Indomethacin	AMI
Ketorolac	GI bleeding
Benzodiazepines	Hip Fracture
Valproic acid	Acute Liver Injury
Carbamazepine	Acute Liver Injury
Amoxicillin	Anaphylactic Shock



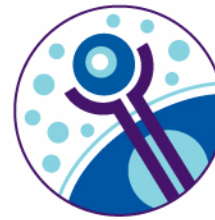
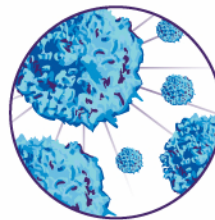
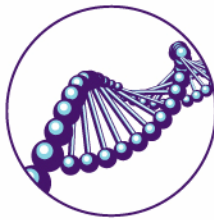
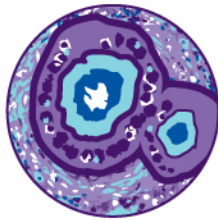
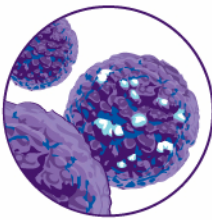
# Conclusions

- The clear conceptual differences between OMOP and Mini-Sentinel CDMs had limited impact on identifying known safety associations in Humana data at the data model level.
- Strikingly different risk estimation can occur at an ecosystem level, but this is primarily attributed to the choices of analytic approach and their implementation in the community developed analytic tools.
- There is a need for ongoing efforts to ensure sustainable and transparent platforms to maintain and develop CDMs and associated tools for effective safety surveillance.

# Acknowledgement

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Thank you!



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