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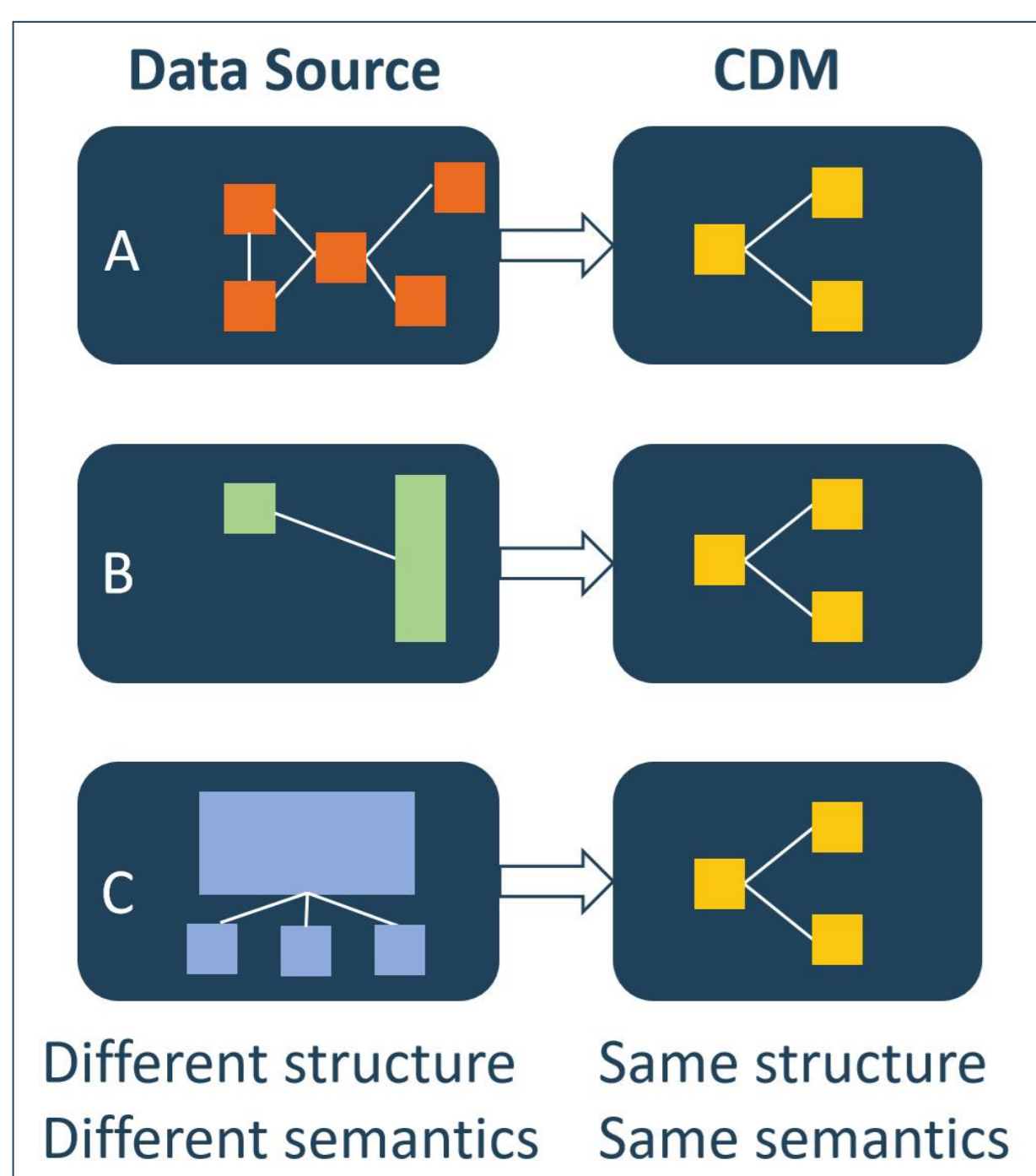
## Background

### Multi-database analyses:

- larger sample size
- more generalizable evidence
- questions related to rare exposures and outcomes



Pharmacoepidemiologic studies



Information content varies greatly between databases, complicating analyses and interpretation of results across databases

Common data models (CDMs) were developed to standardize data structures, format, and meaning

## Results

309 studies were from 36 countries with 1,522 authors, and published in 164 journals, covering 12 types of CDMs

The median number of centers was 7 (IQR 4-8), with a median sample size of 267,182 (interquartile range 16,228-1,531,144)

The top 5 CDMs used: VSD (52.8%), OMOP (24.3%), Sentinel (6.1%), Mini-sentinel (4.5%), and PCORnet (4.5%)

79.9% of the studies utilized the data sources from the US

Korea (18.4%), China (2.6%), and Japan (2.6%) contributed most of Asian data

Only 16 studies used reporting guidelines, and all of these employed the STROBE guidelines

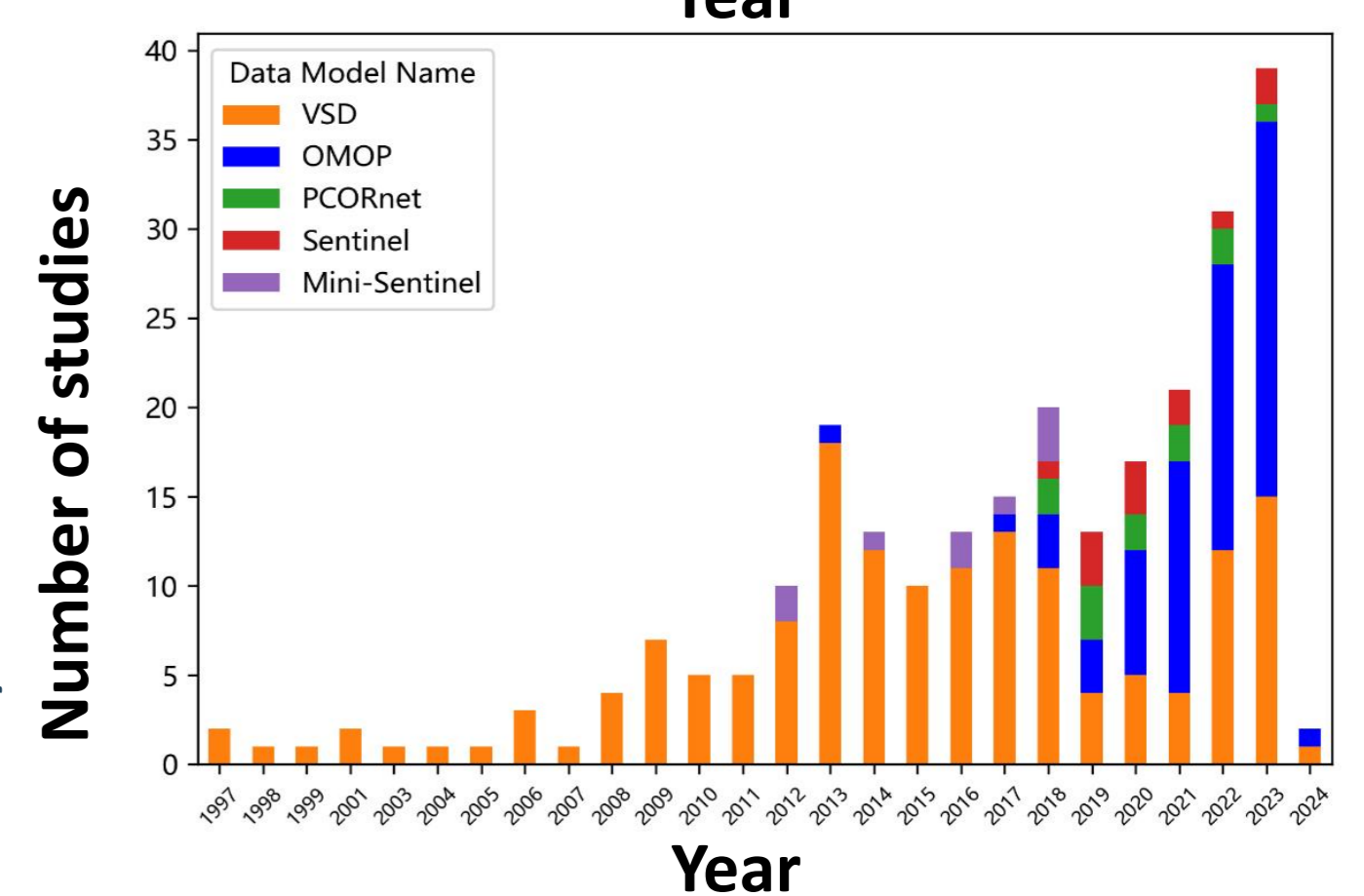
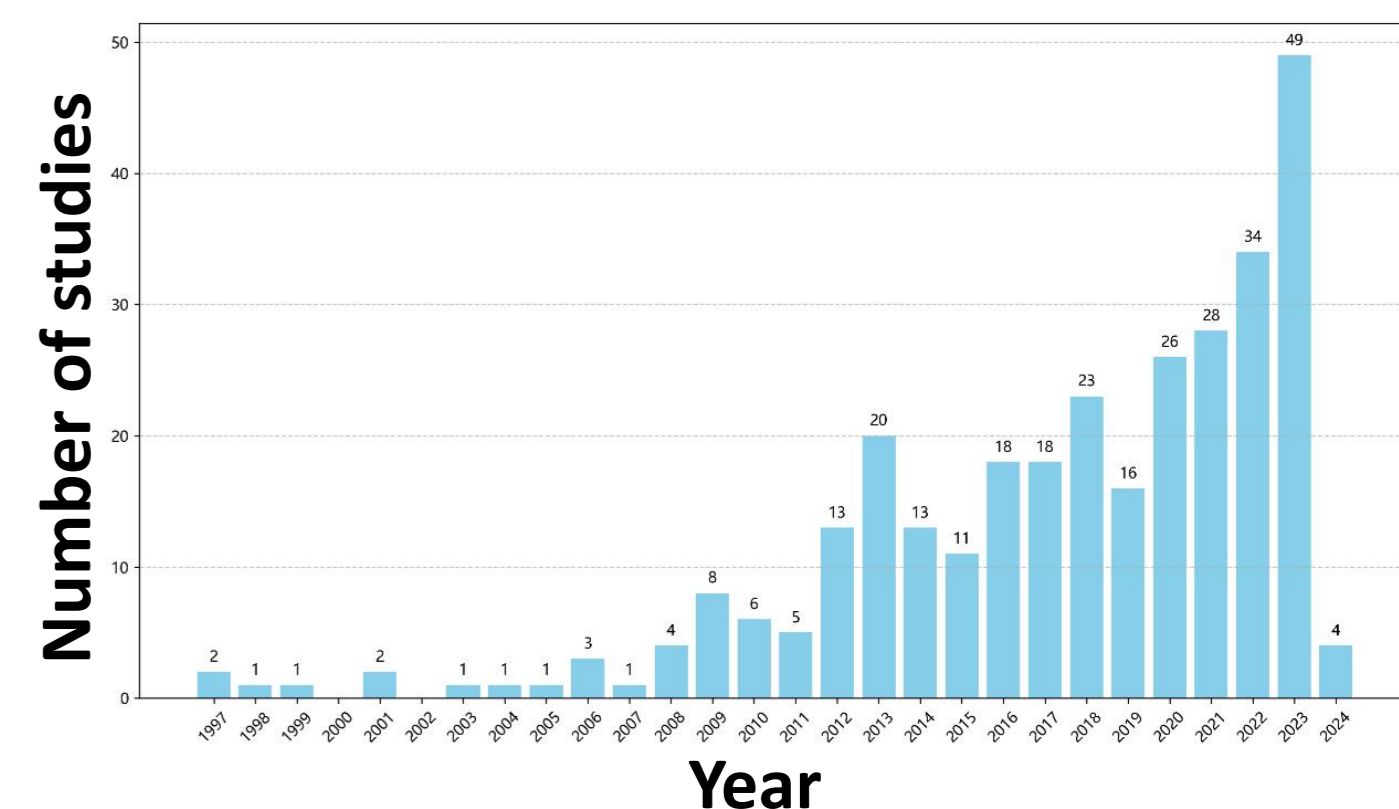


Table 1. 11 types of CDMs used in the world

CDMs	Institutions
VSD	CDC
CRN-VDW	CRN
i2b2	NIH
Sentinel	FDA
OMOP	OHDSI
AsPEN	ACPE
FHIR	HL-7
PCORnet	PCORI
PEDSnet	PCORI
CDASH	CDISC
ConcePTION	IMI

The application of the CDMs in pharmacoepidemiologic research remain unclear

To systematically summarize global work on the use of CDMs in pharmacoepidemiologic research

**Study type**

- The focus was on vaccines in 56.0% of the studies, drugs in 43.4%, and devices/surgeries in 0.6%
- The most commonly studied vaccines were influenza vaccines (54/173) and COVID-19 vaccines (21/173)
- Primary drugs included antidiabetic drugs (21/134) and antibiotics (12/134)

**Research directions**

- Safety (77.3%), drug/vaccine utilization (17.2%), effectiveness (8.0%), and others
- Safety events were primarily concentrated on the nervous systems diseases (58/237) and autoimmune diseases (49/237), maternal and infant outcomes (43/237)

## Methods

### Database

- Five English databases (PubMed, Web of Science, EMBASE, Scopus, Virtual Health Library) and four Chinese databases (CNKI, Wan-Fang Data, VIP, SinoMed)

### Search strategy

- Combination of Chinese and English search terms: “common data model”, “Observational Health Data Sciences and Informatics”, “Observational Medical Outcomes Partnership”, etc.



Language: English and Chinese

From database inception to Jan 2024

### Inclusion criteria

- 1) The CDM (OMOP, CDASH, PCORnet, SDTM, i2b2, etc.) was used to answer questions in the field of drugs/vaccines/medical devices
- 2) Research areas included safety, effectiveness, utilization and accessibility, economic evaluation of all types of drugs, vaccines, and medical devices
- 3) The drug/vaccine/device must be the primary exposure or outcome

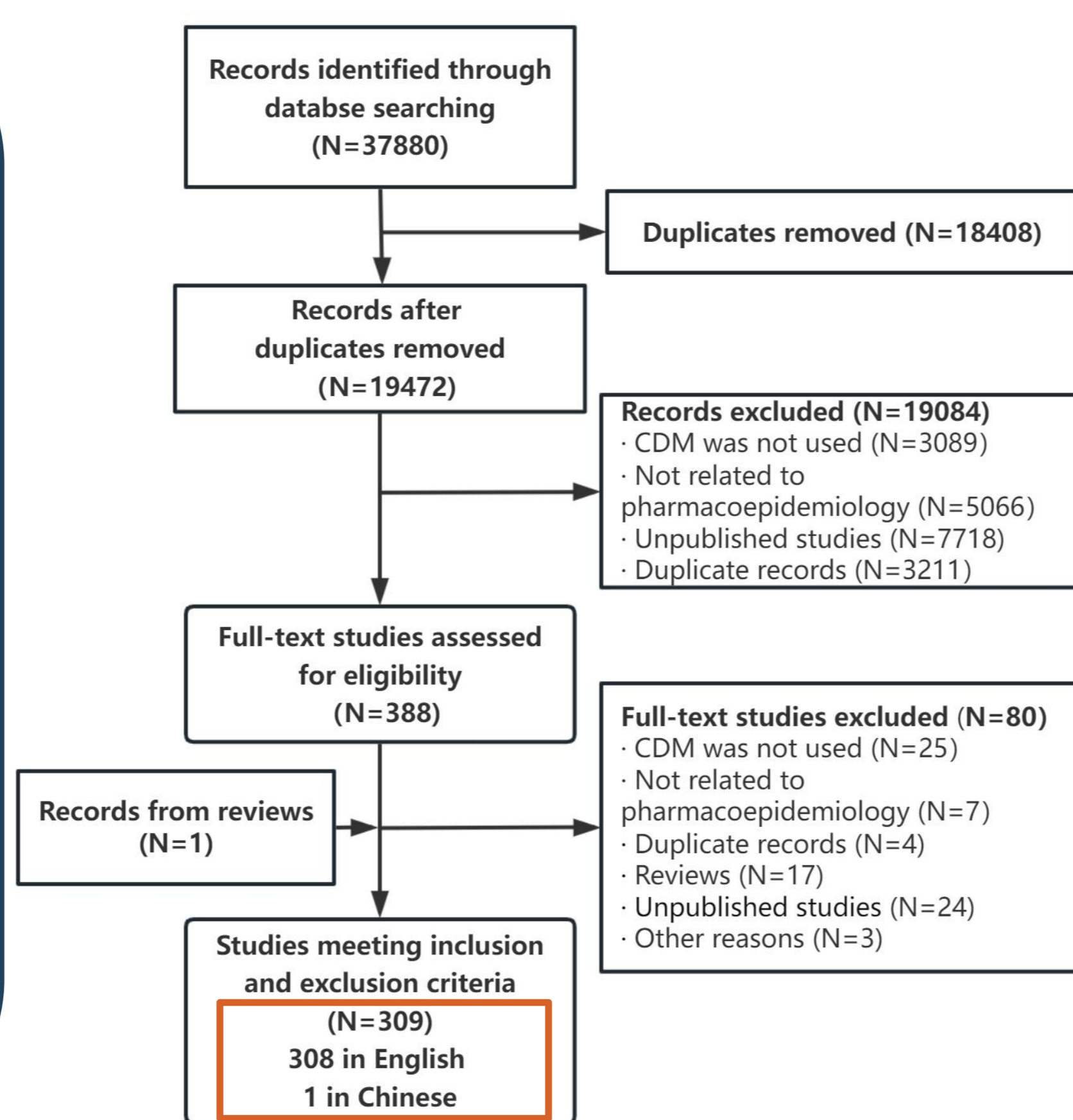


Figure 1. Flow diagram for study selection.

## Conclusions

Our study provides a comprehensive perspective on all CDMs, related drugs/vaccines and treatment areas, identifying the feasibility of CDMs in pharmacoepidemiologic studies

The future direction of CDM applications still needs further expansion, with a focus on enhancing the standardization of research reports

We call on researchers from Asian countries to focus on and increase their participation in CDM applications and multicentre research to generate more representative studies

We have also compiled the common bias of CDMs in pharmacoepidemiologic studies, and the article is still in the process of being written

Bibliometric analysis and more detailed analysis are still under study

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VSD, Vaccine Safety Datalink; CDC, Center for Disease Control; CRN-VDW, Cancer Research Network-Virtual Data Warehouse; CRN, Cancer Research Network; i2b2, Informatics for Integrating Biology & the Bedside; NIH, National Institute of Health; FDA, Food and Drug Administration; OMOP, Observational Medical Outcomes Partnership; OHDSI, Observational Health Data Sciences and Informatics; AsPEN, Asian Pharmacoepidemiology Network; ACPE, Asian Conference on Pharmacoepidemiology; FHIR, Fast Healthcare Interoperability Resources; HL7, Health Level Seven; PCORnet, Patient-Centered Clinical Research Network; PCORI, Patient-Centered Outcomes Research Institute; CDASH, Clinical Data Acquisition Standards Harmonization; CDISC, Clinical Data Interchange Standards Consortium; IMI, Innovative Medicines Initiative.