

## 2024 OHDSI APAC Lightning Talk

# Feasibility of Integrating DICOM Headers into the OMOP Medical Imaging CDM : A Pilot Study Using Chest CT Data

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# Medical Imaging CDM (MI-CDM)

- **The OHDSI Medical Image Workgroup** proposed two new tables to the OMOP CDM, the medical imaging extension model

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<https://doi.org/10.1007/s10278-024-00982-6>

Check for updates

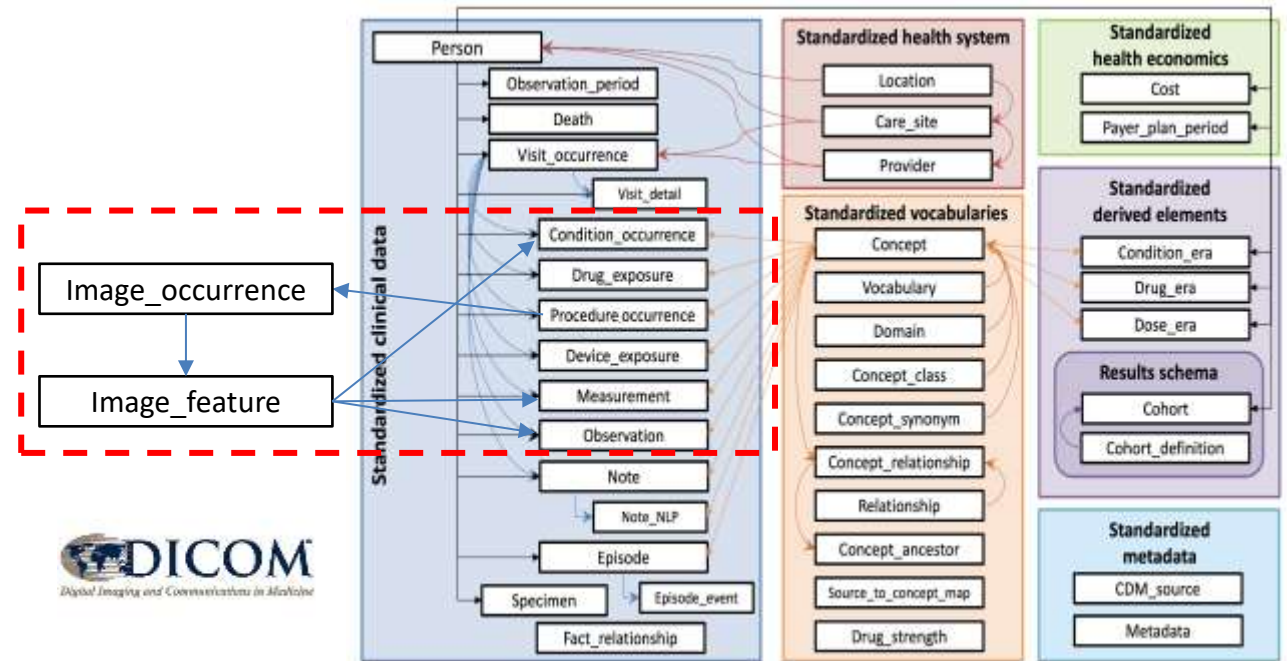
## Development of Medical Imaging Data Standardization for Imaging-Based Observational Research: OMOP Common Data Model Extension

Woo Yeon Park<sup>1</sup> · Kyulee Jeon<sup>2,3</sup> · Teri Sippel Schmidt<sup>1</sup> · Haridimos Kondylakis<sup>4</sup> · Tarik Alkasab<sup>5</sup> · Blake E. Dewey<sup>6</sup> · Seng Chan You<sup>2,3</sup> · Paul Nagy<sup>1</sup>

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**Abstract**  
The rapid growth of artificial intelligence (AI) and deep learning techniques require access to large inter-institutional cohorts of data to enable the development of robust models, e.g., targeting the identification of disease biomarkers and quantifying disease progression and treatment efficacy. The Observational Medical Outcomes Partnership Common Data Model (OMOP CDM) has been designed to accommodate a harmonized representation of observational healthcare data. This study proposes the Medical Imaging CDM (MI-CDM) extension, adding two new tables and two vocabularies to the OMOP CDM to address the structural and semantic requirements to support imaging research. The tables provide the capabilities of linking DICOM data sources as well as tracking the provenance of imaging features derived from those images. The implementation of the extension enables phenotype definitions using imaging features and expanding standardized computable imaging biomarkers. This proposal offers a comprehensive and unified approach for conducting imaging research and outcome studies utilizing imaging features.

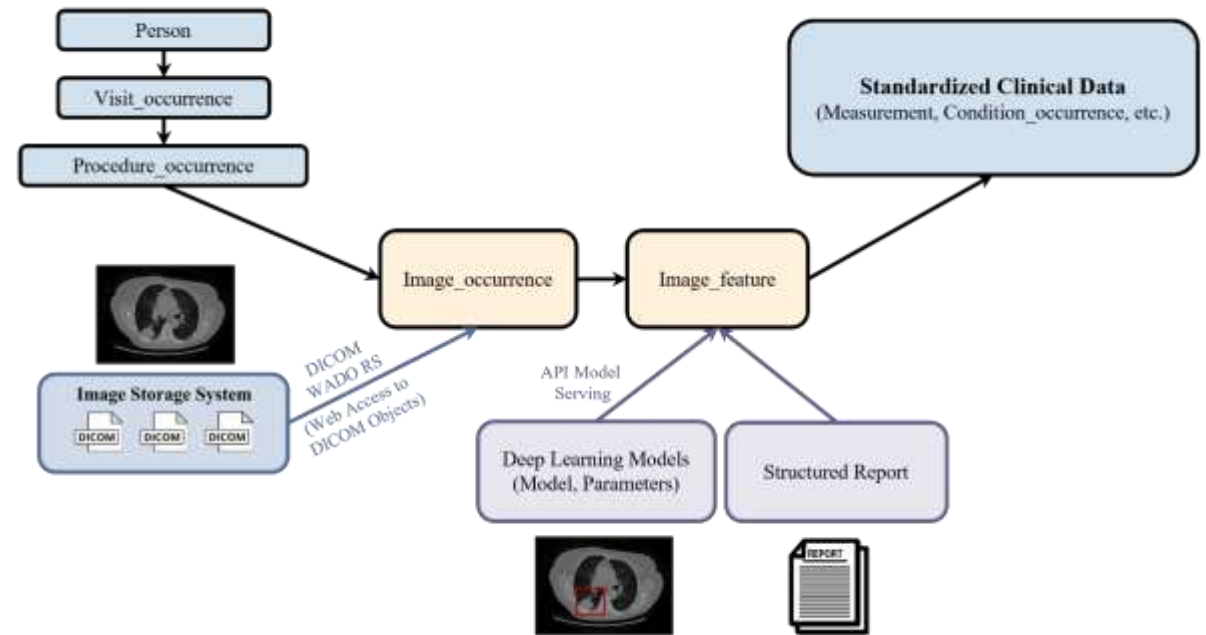
**Keywords** Data collection [MeSH] · Data standardization · Observational research · Data integration · Multimodal data analysis





# Imaging Goals with OHDSI

- Bring **features** derived from medical images into data model while **maintaining provenance**
  - E.g. Lung nodule's size detected by AI
  - E.g. CT slice thickness recorded in DICOM
- Perform **cohort definitions** in OHDSI for **medical imaging studies**
  - E.g. Find the Chest CT Scans with a slice thickness of <2.5 mm for patients ultimately diagnosed with lung cancer



[Fig 1. Framework of Medical Imaging CDM]



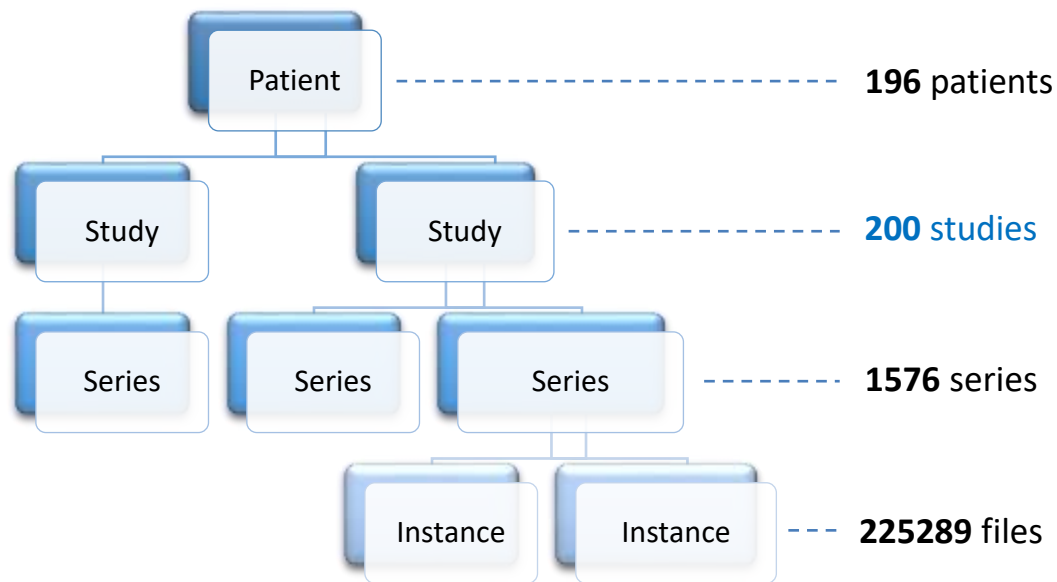
# Pilot Study: Objectives

- Implement the MI-CDM **using real-world imaging data** and evaluate the feasibility of **integrating DICOM headers** into the MI-CDM framework

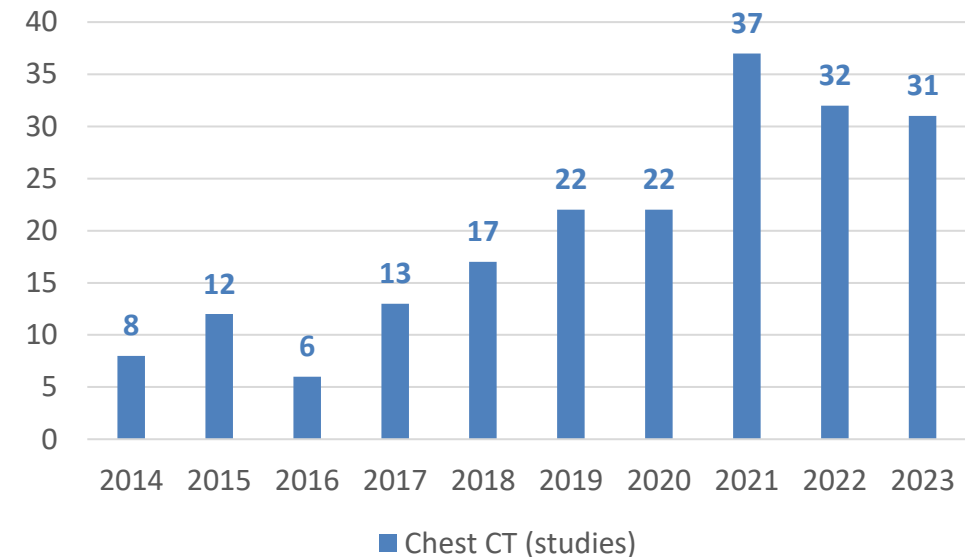


# Data Source

- Severance Hospital, Seoul, South Korea
  - **200 chest CT scans** from 196 lung cancer patients (diagnosed 2014-2023)



[Fig 2. Hierarchical Structure of the DICOM Dataset]

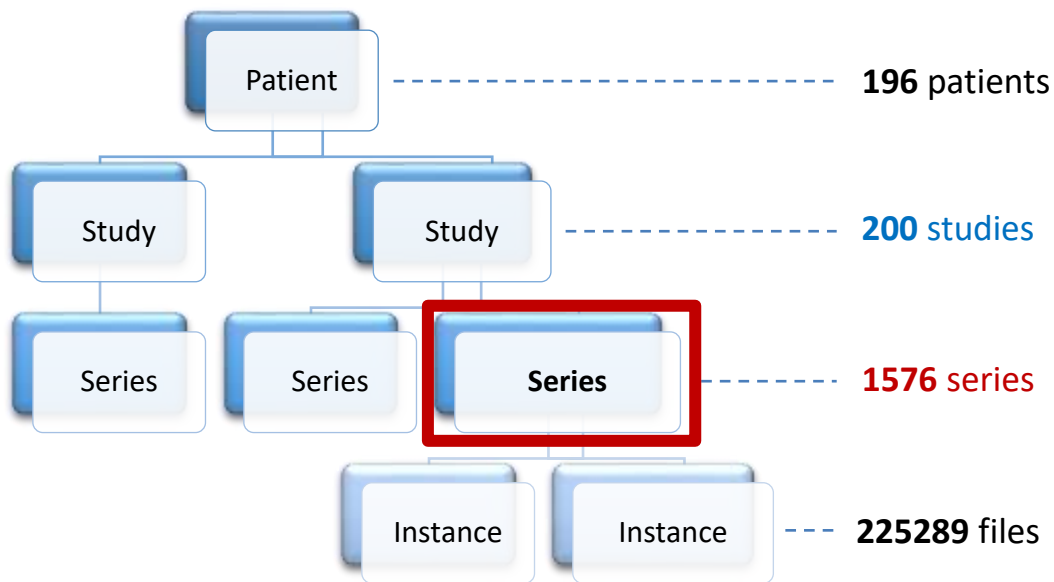


[Fig 3. Yearly Distribution of Chest CT Dataset (2014-2023)]




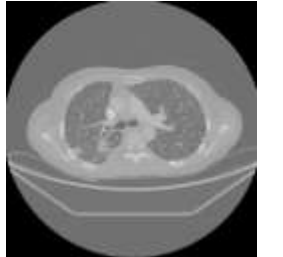
# Data Source

- Severance Hospital, Seoul, South Korea
  - 200 chest CT scans from 196 lung cancer patients (diagnosed 2014-2023)



[Fig 2. Hierarchical Structure of the DICOM Dataset]

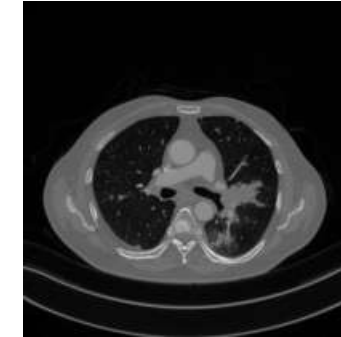
(Example: Different series within same study for single patient at same time)

| (PAT123, 2020.10.23)  | Series #1  | Series #2  |
|-----------------------|--|--|
| SliceThickness        | 800  | 2.5  |
| KVP                   | 120  | 100  |
| ScanOptions           | SCOUT MODE   | HELICAL MODE   |
| ContrastBolusVolume   | 100  | 94   |
| Pixel Image (Example) |  |  |



# DICOM Dataset

- DICOM Metadata
  - **Descriptive information** about the patient, study, and imaging parameters.
  - Pixel values depend on metadata such as **acquisition parameters**.
- Link DICOM metadata to OMOP for imaging data discovery, retrieval, and analysis.



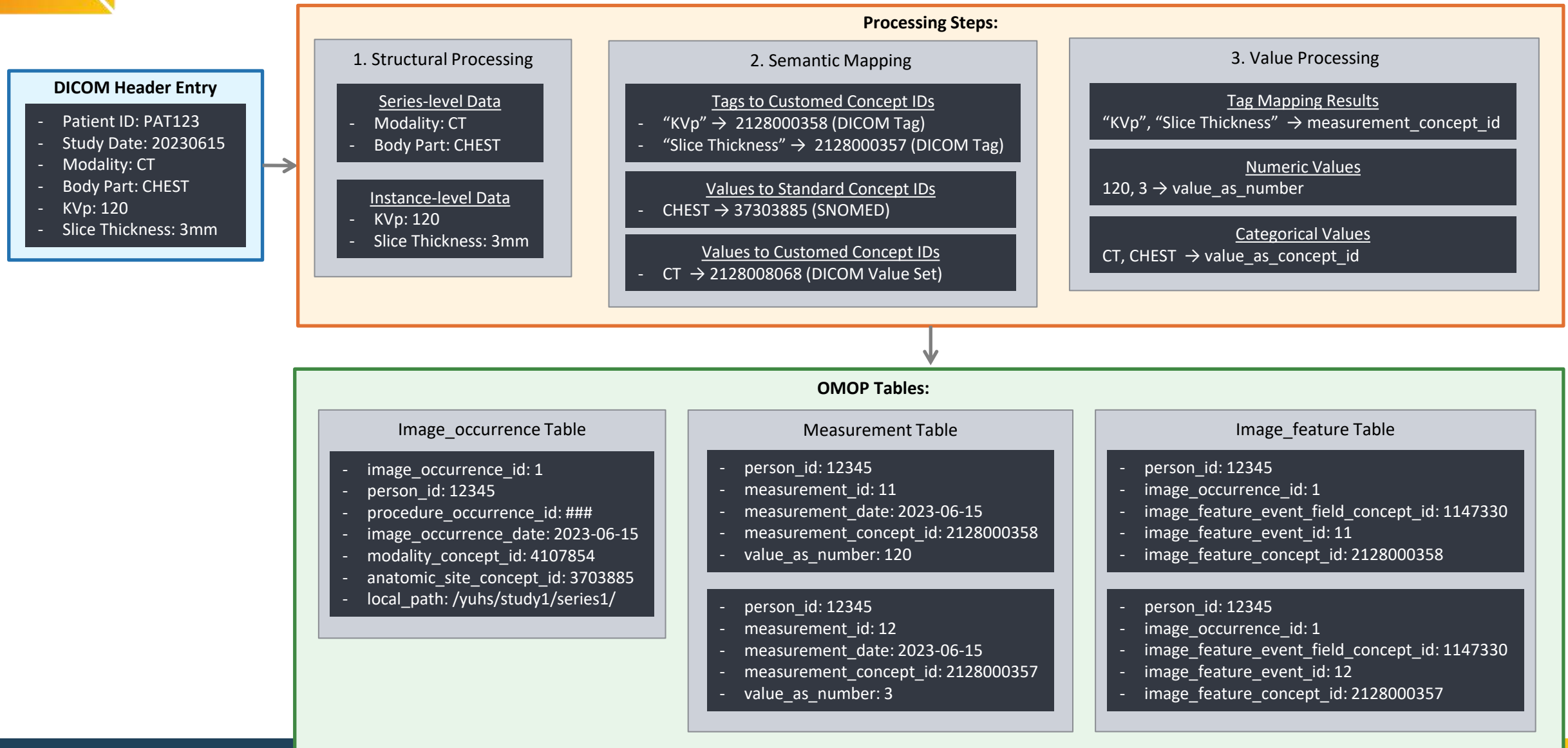
| Tag         | Attribute Name            | Value (example)        |
|-------------|---------------------------|------------------------|
| (0010,0040) | Patient's Sex             | M                      |
| (0010,1010) | Patient's Age             | 067Y                   |
| (0008,0020) | Study Date                | 20190101               |
| (0008,0060) | Modality                  | CT                     |
| (0018,0015) | Body Part Examined        | CHEST                  |
| (0008,0070) | Manufacturer              | Siemens Healthineers   |
| (0008,1090) | Manufacturer's Model Name | SOMATOM Force          |
| (0018,0050) | Slice Thickness           | 1                      |
| (0018,0060) | KVP                       | 100                    |
| (0018,1041) | Contrast/Bolus Volume     | 0                      |
| (0018,9345) | CTDIvol                   | 4.13998747826087 (mGy) |

[Table 1. DICOM Metadata Example for a Chest CT Image]





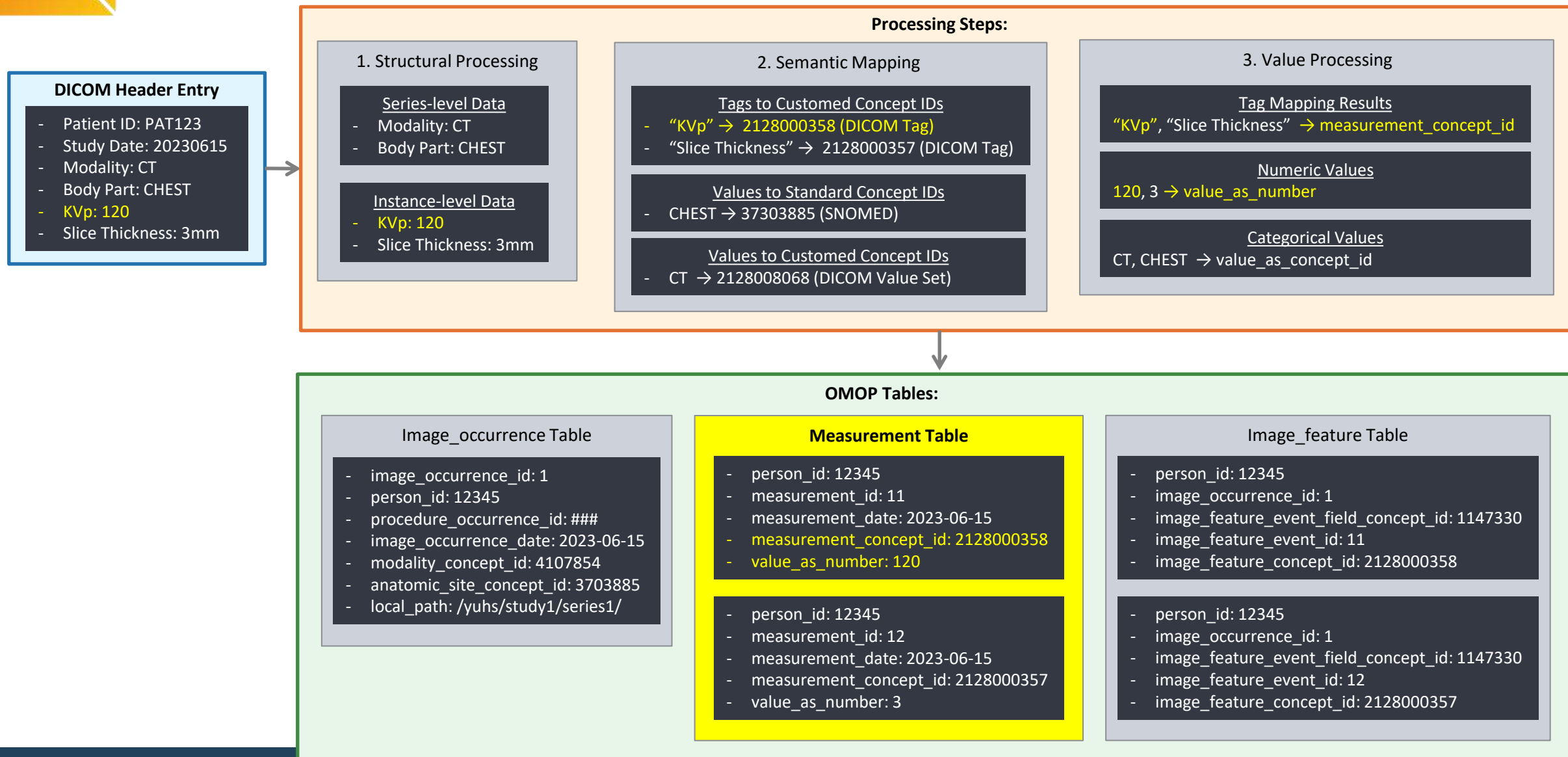
# DICOM to OMOP ETL Process with an Example







# Example: A DICOM Parameter (KVp) into OMOP

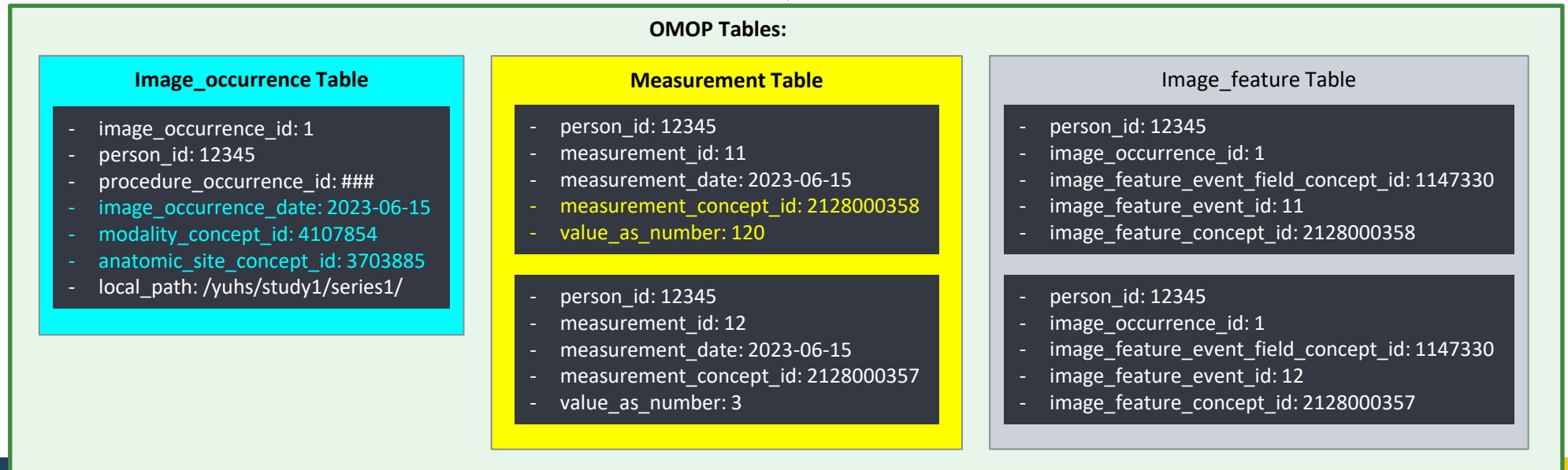
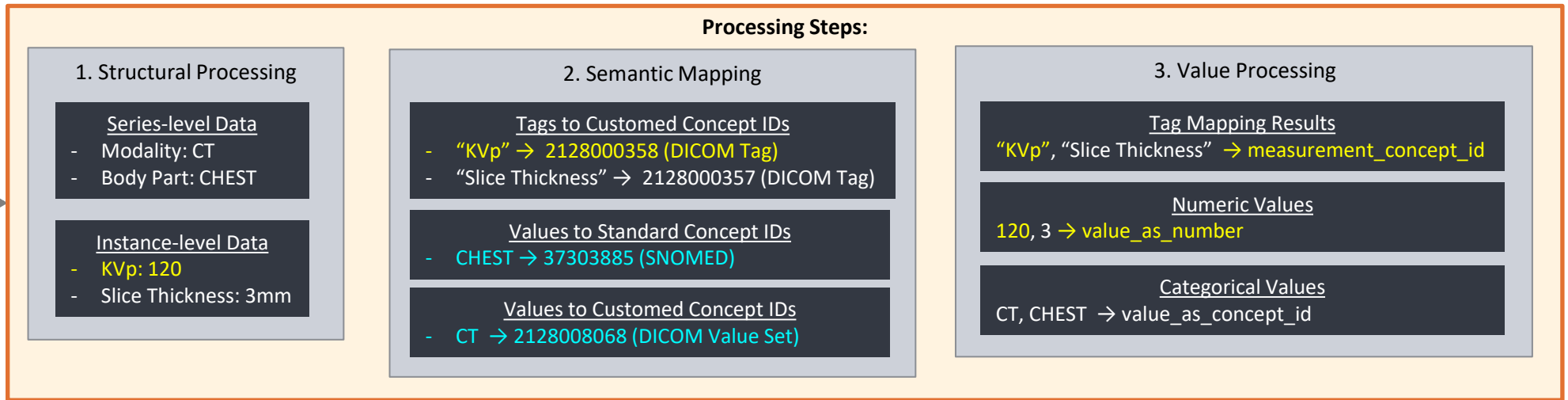




# Example: Series-level Imaging Provenance

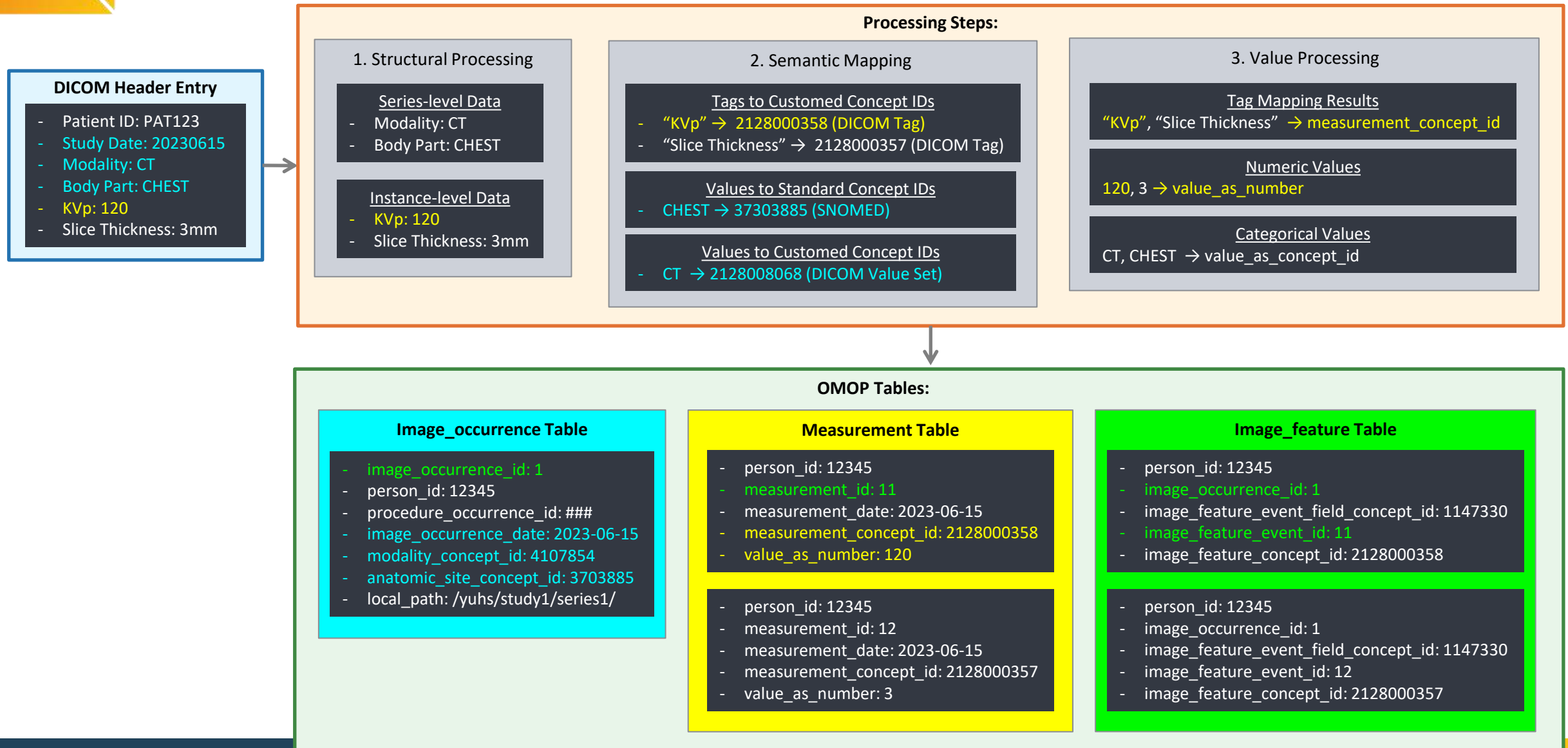
**DICOM Header Entry**

- Patient ID: PAT123
- Study Date: 20230615
- Modality: CT
- Body Part: CHEST
- KVp: 120
- Slice Thickness: 3mm



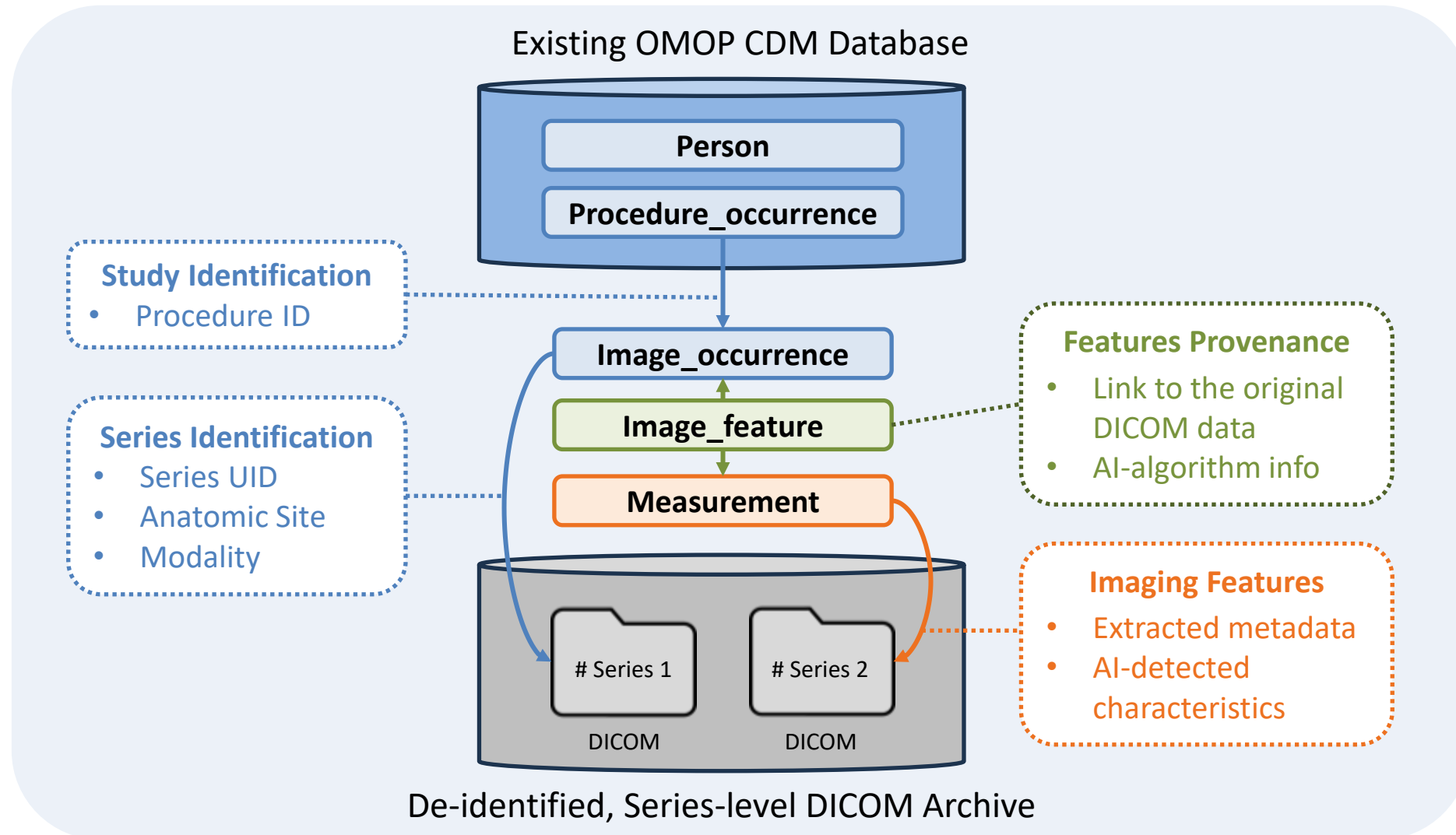


# DICOM to OMOP ETL Process with an Example





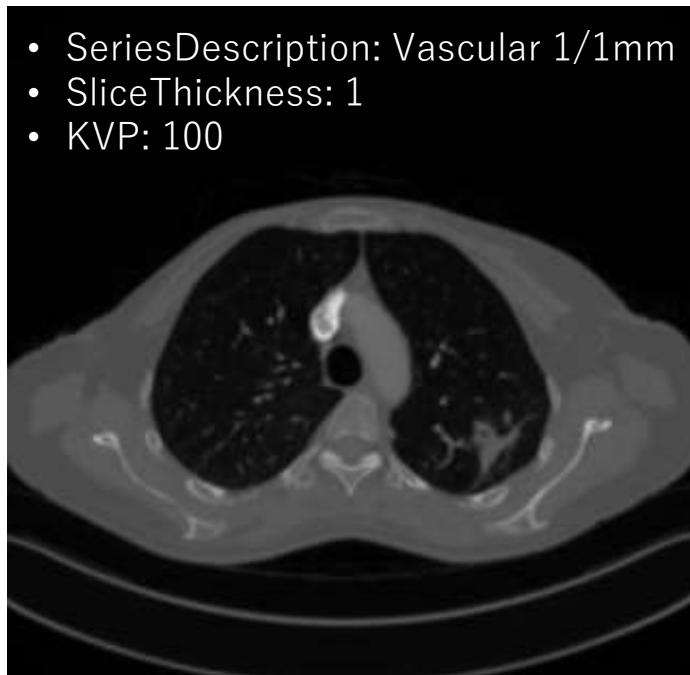
# MI-CDM Workflow





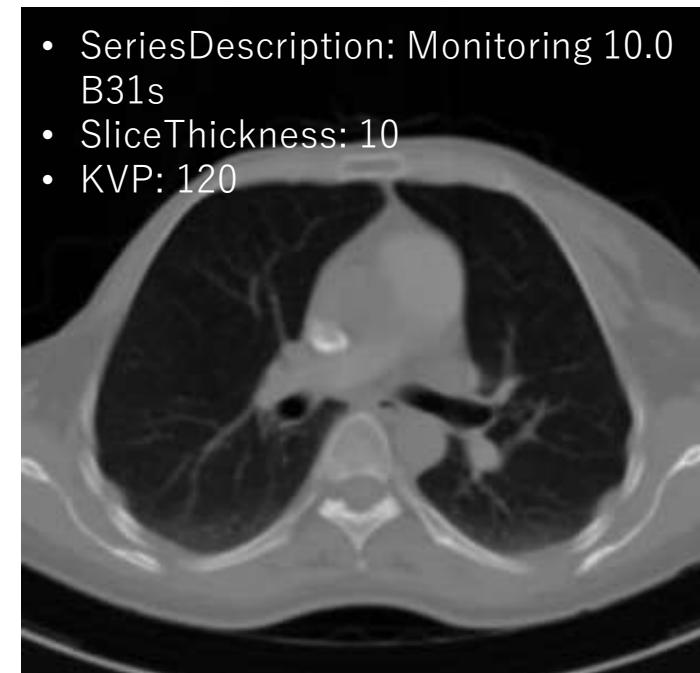
# Use Case Example

- Define a cohort of lung cancer patients who underwent chest CT scans within 7 days of surgery.
- Retrieve imaging series with a slice thickness  $\leq 1$  mm.



Same study, but  
higher resolution

>

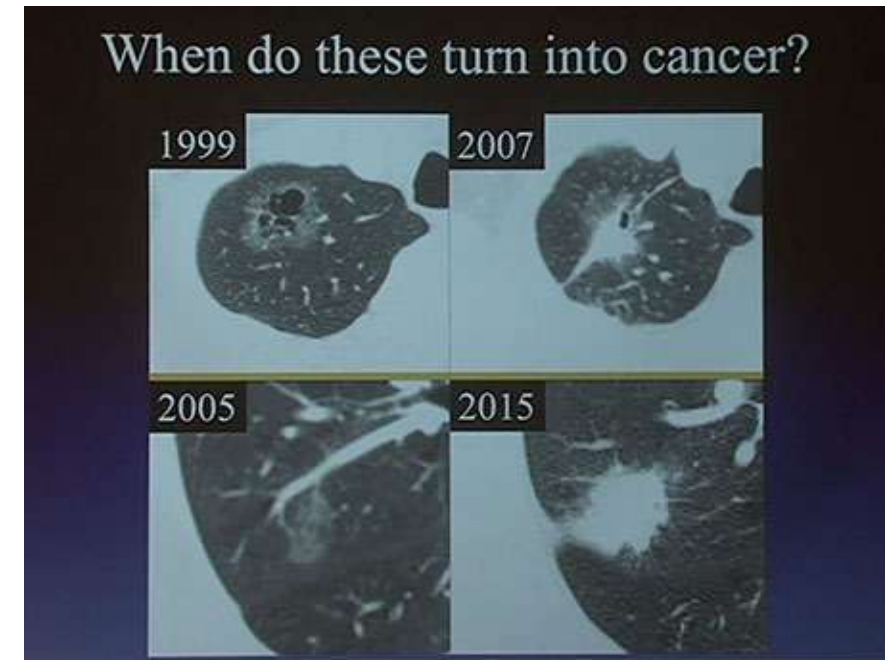


[Fig 4. Different series within the same chest CT study (same patient, same day)]



# Conclusion

- Enhanced **imaging data retrieval** based on patient and imaging parameters.
- Incorporating **pixel phenotypes** into the OMOP CDM broadens the scope of capturing the patient journey.





# Acknowledgement

## **Special thanks to the OHDSI Medical Image Workgroup:**

Jen Woo Yeon Park, M.S.,

Teri Sippel Schmidt, M.S.,

Blake Dewey, Ph.D.,

Paul Nagy, Ph.D.,

Seng Chan You, M.D., Ph.D.



# Thank you!

Join the OHDSI community and Medical Imaging Working Group

<https://www.ohdsi.org/join-the-journey/>



Additional information on OMOP CDM Medical Imaging extension can be found here.

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# **Risk of aortic aneurysm or dissection following use of fluoroquinolones: a multinational network cohort study**

**Jack L Janetzki<sup>1,\*</sup>, Jung Ho Kim,<sup>2,\*</sup> Nicole Pratt,<sup>1</sup> and Seng Chan You,<sup>3,4</sup> on behalf to the 2023 OHDSI SOS Challenge Fluoroquinolone team**



# Background

December 2018:

The screenshot shows the FDA website header with the logo and navigation links. The main content area features a large heading: "FDA warns about increased risk of ruptures or tears in the aorta blood vessel with fluoroquinolone antibiotics in certain patients". Below the heading, it is identified as an "FDA Drug Safety Communication".

**FDA warns about increased risk of ruptures or tears in the aorta blood vessel with fluoroquinolone antibiotics in certain patients**

*FDA Drug Safety Communication*

April 2019:

The screenshot shows the Australian Government website header with the logo and navigation links. The main content area features a heading: "Fluoroquinolone antibiotics and risk of aortic aneurysm/dissection". Below the heading, it is identified as a "Medicines Safety Update" published on "12 April 2019".

**Fluoroquinolone antibiotics and risk of aortic aneurysm/dissection**

Medicines Safety Update

Published: 12 April 2019



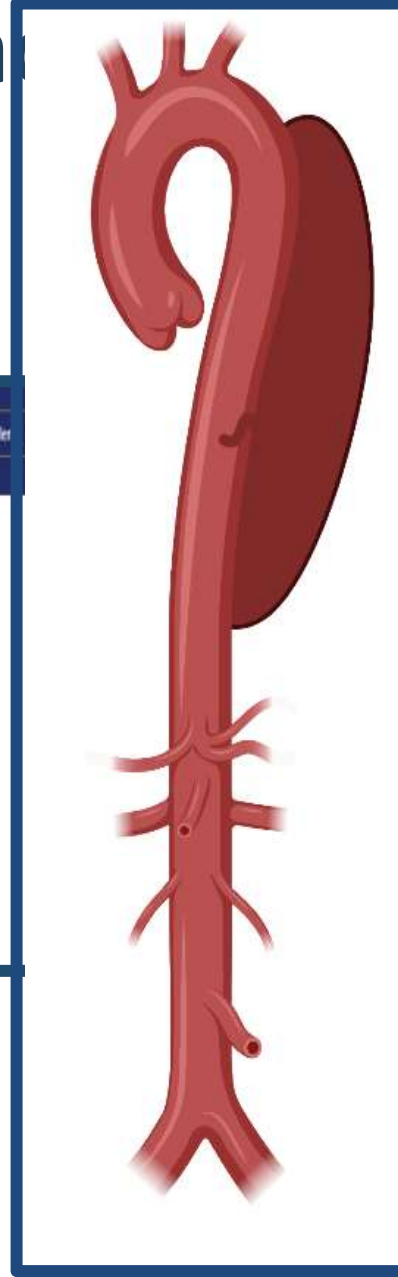
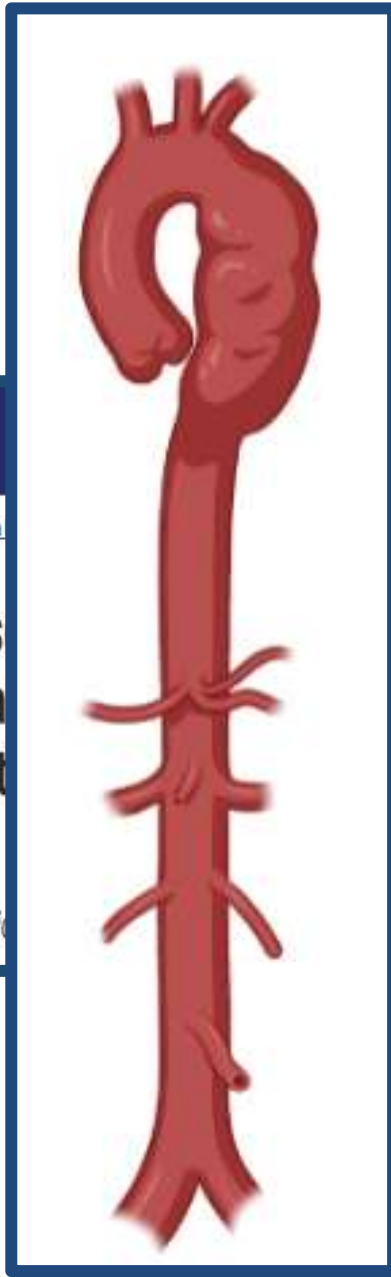
December 2018:

**FDA** U.S. FOOD & DRUG  
ADMINISTRATION

[Home](#) / [Drugs](#) / [Drug Safety and Availability](#) / [FDA warns about increased risk of ruptures or tears in the aorta with fluoroquinolone antibiotic patients](#)

## FDA warns about increased risk of ruptures or tears in the aorta with fluoroquinolone antibiotic patients

FDA Drug Safety Communication



9:

and Aged Care  
Administration

Search

Product safety   How we regulate   Guidance and resources

[Safety updates](#)

## Fluoroquinolone antibiotics and risk of aortic dissection

2019



# What evidence?

- Safety announcement based on:
  - Cases reported to FDA
  - 4 published studies providing moderate quality evidence
    - Inconsistencies in study designs (active comparators, follow-up, patient age, inclusion of specific fluoroquinolones)
    - Conflicting results
- Researchers aware of limitations of prior studies



# What did we do?





# Study

- 1. Characterization:** incidence and time-to event of aortic events following fluoroquinolone exposure
- 2. Estimation:** comparative safety of fluoroquinolones vs other antibiotics

Were people **more likely to go to hospital for internal bleeding within 60 days** of starting certain antibiotic treatment **for treatment of urinary tract infections** compared to people who received other commonly used antibiotics?

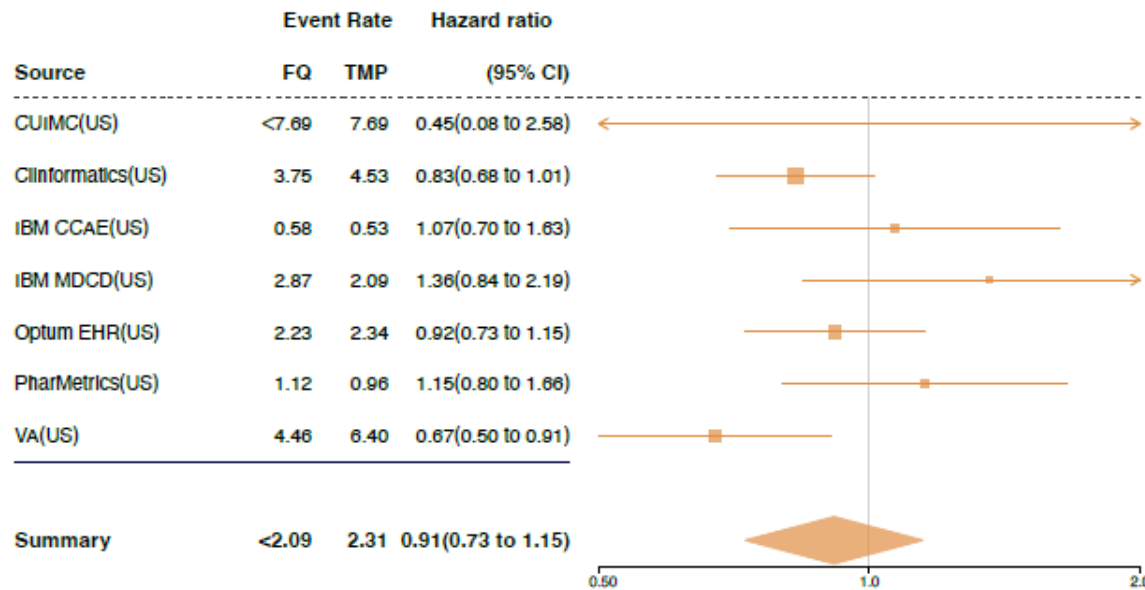


# Findings?

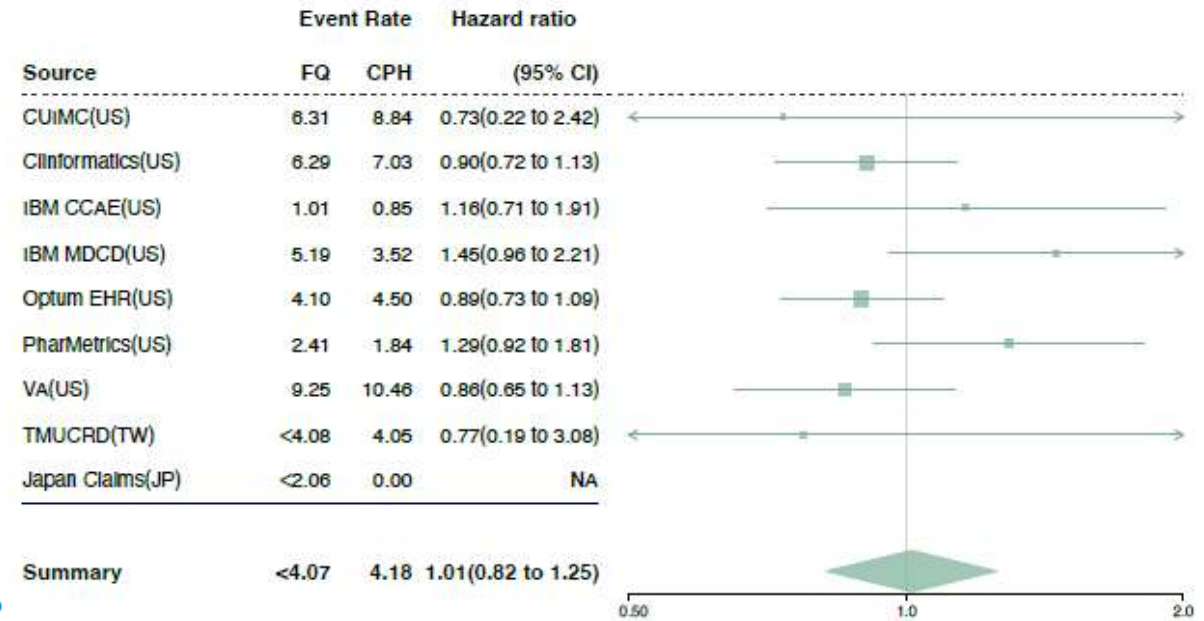


- Implemented OHDSI's objective study diagnostics
- > 13.5 million people
- 14 different databases from 5 different countries

**FQ vs TMP**



**FQ vs CPH**

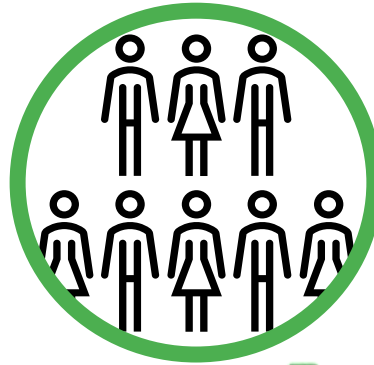




# Findings?



SAFE



SAFE



SAFE





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OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

# Mapping Thai Medicine Terminology to RxNorm: Lesson Learned in Standard Vocabulary Integration

*Krittaphas Chaisutyakorn (Krit)  
Thailand*



# Introduction



- Siriraj Hospital is currently transforming its EHR data to OMOP CDM
- Current vocabulary
  - a. Luckily, we also have Thai Medicine Terminology (TMT) codes which is maintained and use in nation-wide level
  - b. But we still didn't have international/standard level codes
- TASK: Mapping Thai Medicine Terminology (TMT) to RxNorm codes



# Breaking down the task

1. At which level

2. What codes to map

3. How to map

# At which levels?



- Codes which contain Ingredient + Strength + Form are sufficient for most researches

## TMT

amoxicillin 875 mg + clavulanic  
acid  
125 mg film-coated tablet, 1 tablet

## RxNorm

amoxicillin 875 MG / clavulanate  
125 MG Oral Tablet



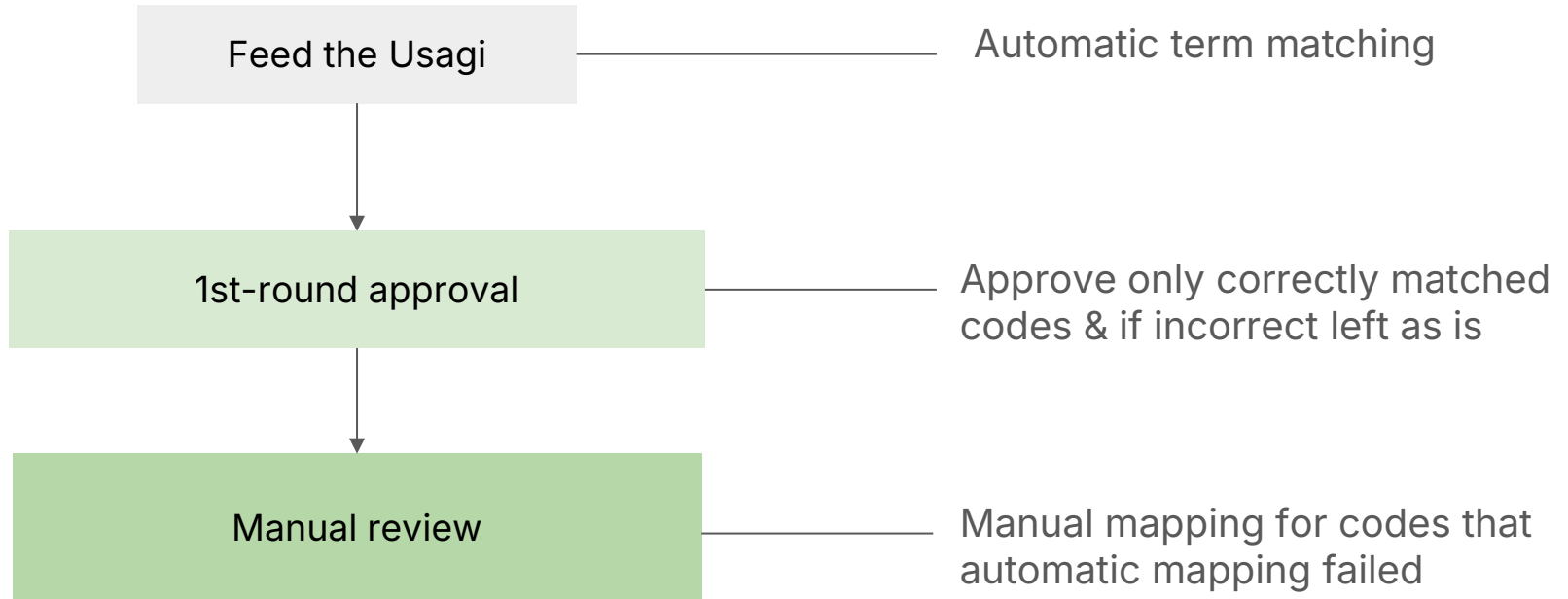
# What codes to map



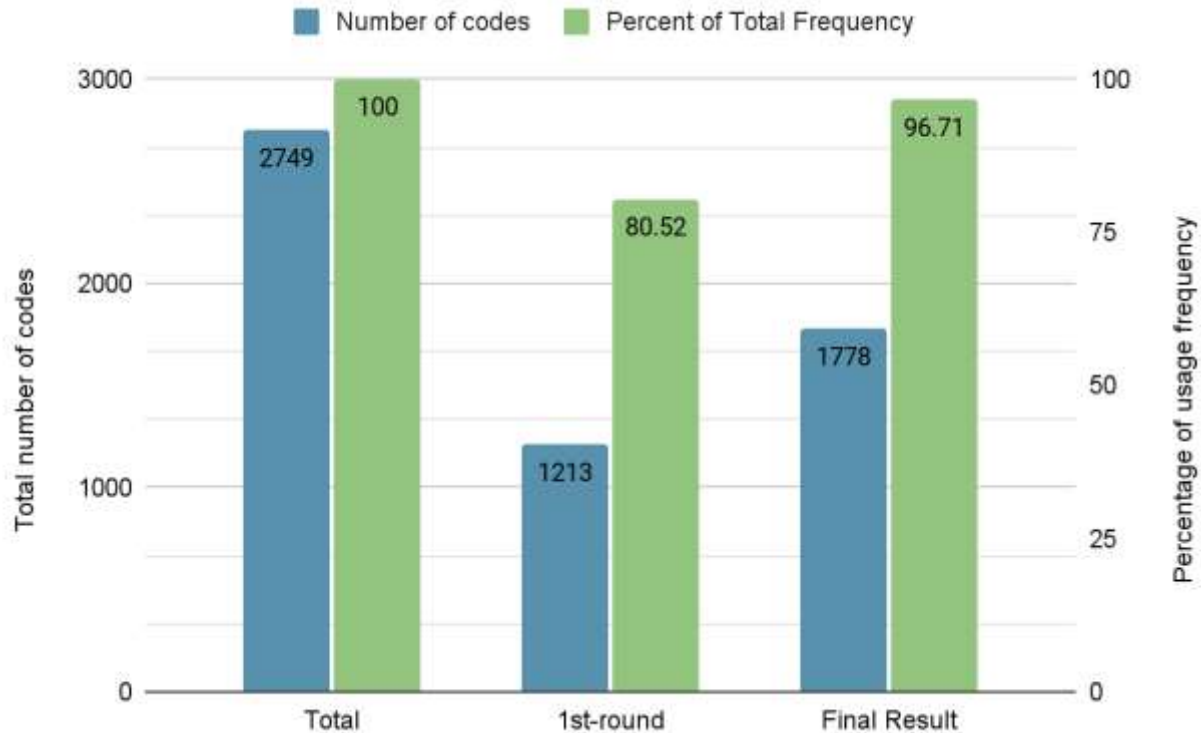
- Siriraj Hospital have 2,749 unique medication codes
- We aim to cover 95% of medication usage frequency



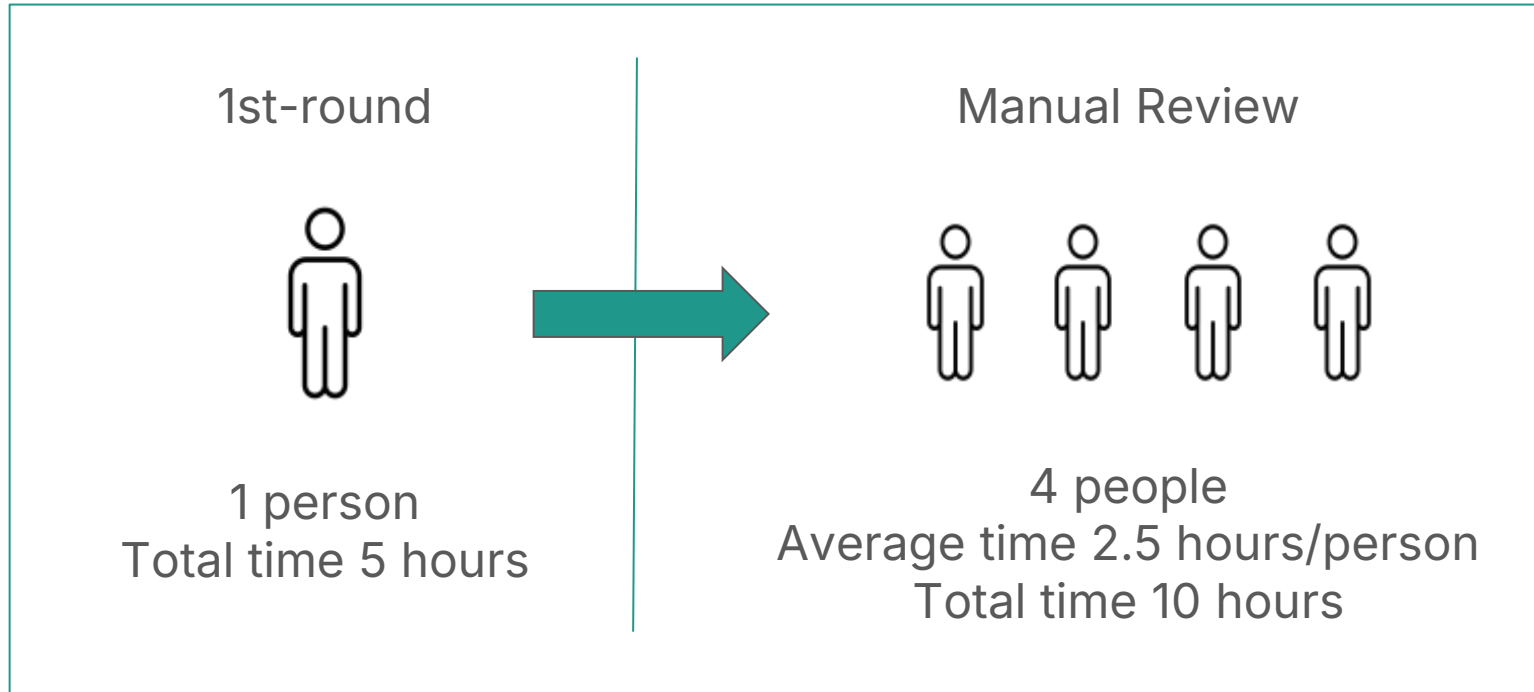
# How to map



# Number of codes and Percentage



# Time investment



All of this processes was done in **3 weeks**



# Lesson Learned



- Challenging medications to be mapped are intravenous medications, combined medications, vaccines
- 60% of medications contribute to 96% of total usage
- Seemingly impossible task can be broken down to smaller achievable tasks, making the whole process much more feasible.





Mahidol University  
Faculty of Medicine  
Siriraj Hospital

Siriraj Informatics and  
Data Innovation Center



# Thank You

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# Enabling Genomic Data Harmonization in OMOP CDM

**Erwin Tantoso<sup>1</sup>, Kee Yuan Ngiam<sup>2,3</sup>, Mukkesh Kumar<sup>1,4</sup>**

<sup>1</sup> Bioinformatics Institute, Agency for Science Technology and Research, Singapore

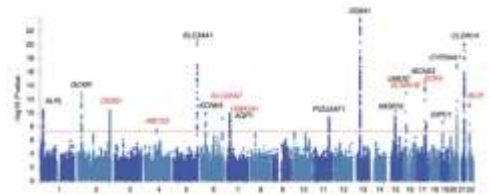
<sup>2</sup> Division of General Surgery (Thyroid & Endocrine Surgery), National University Hospital Singapore, Singapore

<sup>3</sup> Department of Biomedical Informatics, Yong Loo Lin School of Medicine, National University of Singapore, Singapore

<sup>4</sup> Institute for Human Development and Potential, Agency for Science Technology and Research, Singapore



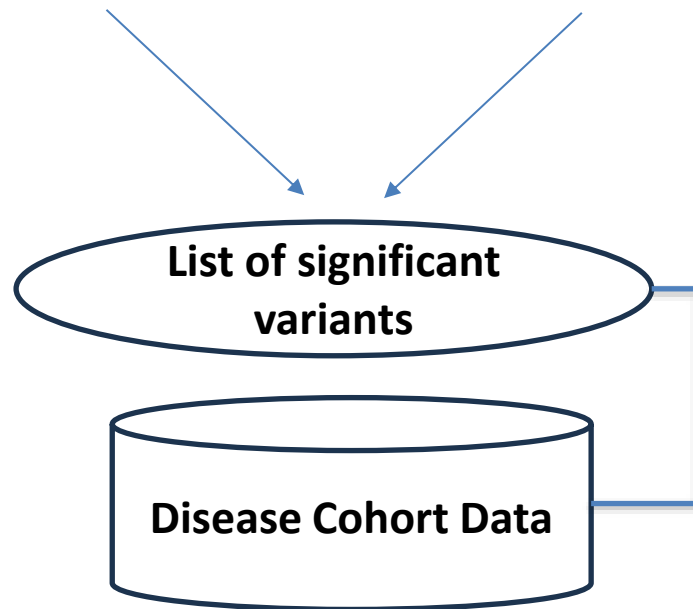
# OMOP CDM enable standardized analytics across a distributed data network



Discovery-based Analysis

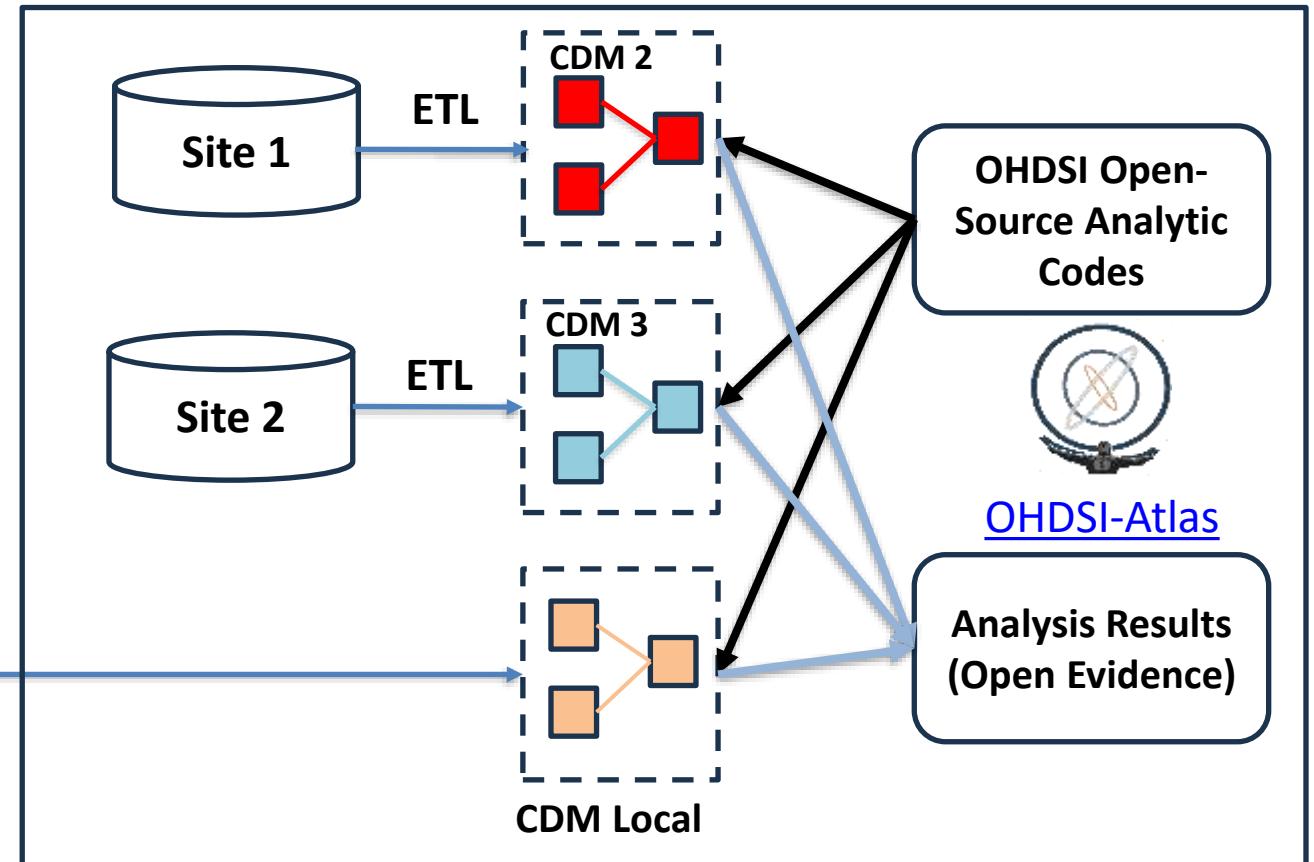


Targeted Gene Panel



ETL

## OHDSI Data Network





# OMOP Genomic for Genetic Data Harmonization in OMOP CDM

- **Challenges:**

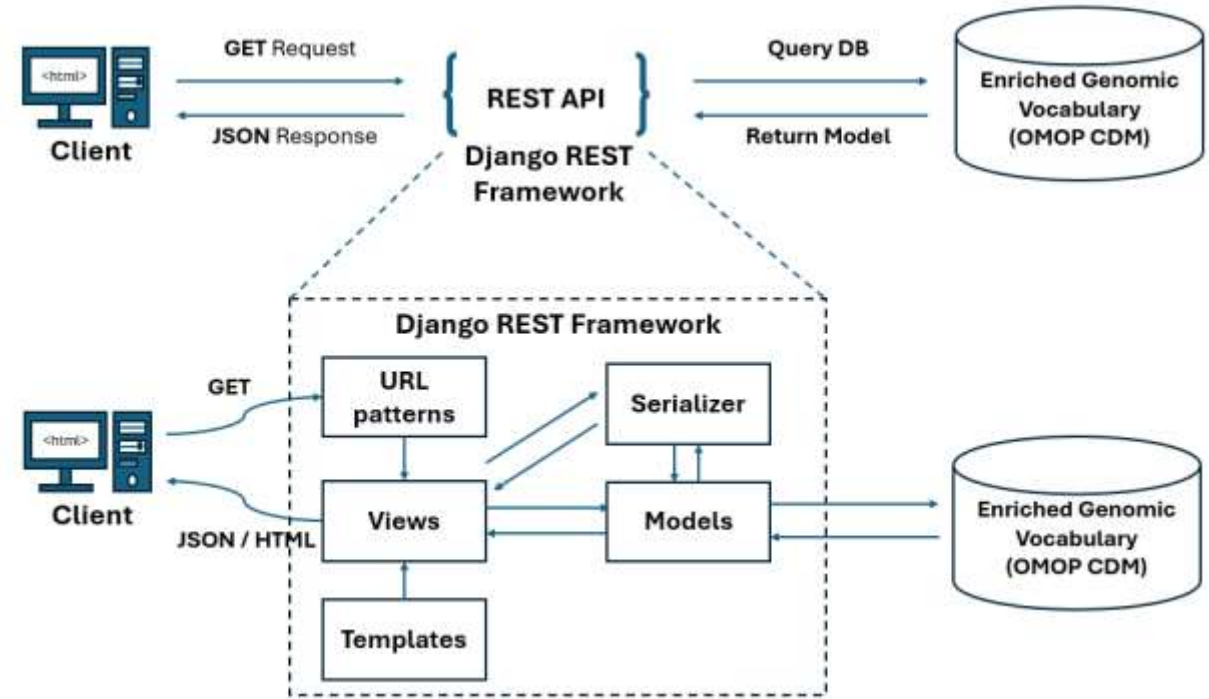
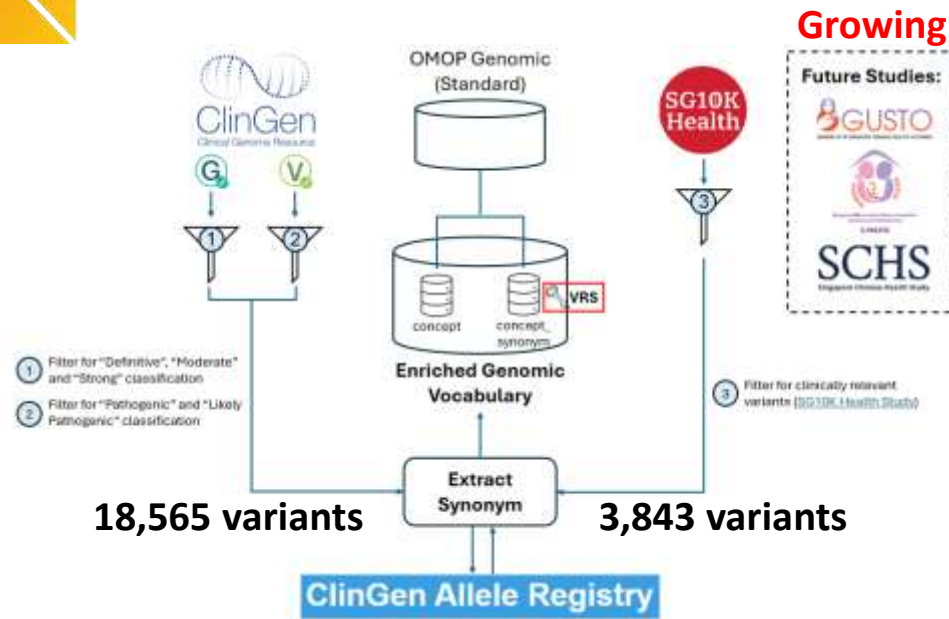
- Limited coverage:
  - OMOP Genomic is designed for oncology research ([Golozar A. and Reich C. 2022](#))
  - Limited coverage on clinically relevant variants in Asian population, especially Singapore
- Technical challenges:
  - Mapping tool for diverse variant representation
  - OMOP CDM conversion

- **Our objectives:**

1. Enriching the genomic vocabulary with clinically relevant variants from publicly available literature/curated datasets in the local Singapore context
2. Allow streamlined transformation of variant data to OMOP CDM space
  - a) Query and mapping tool from variant to OMOP Concept IDs
  - b) Streamlined annotation of variant data with OMOP Concept IDs
  - c) OMOP CDM Genomic Data Transformer

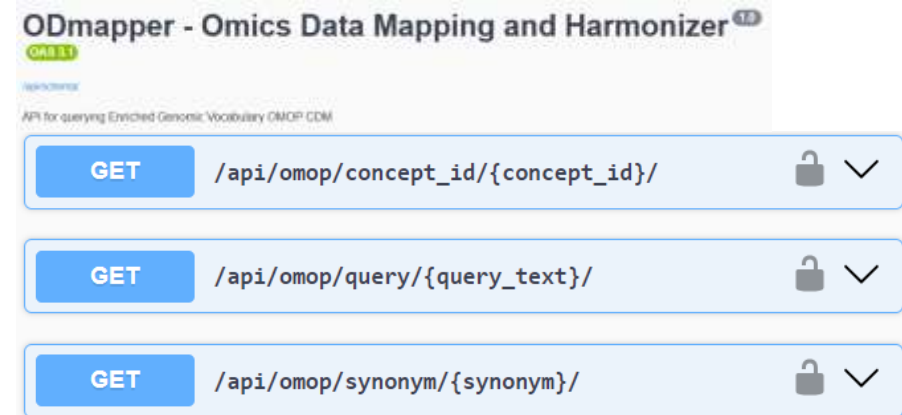


# Methods and Results



| Genes related to phenotype (ACMG v3.2) | #Genes | OMOP Genomic | Enriched Genomic Vocabulary |
|--|--------|--------------|-----------------------------|
| Cancer phenotype                       | 28     | 28           | 28                          |
| Cardiovascular phenotypes              | 40     | 10           | 40                          |
| Inborn errors of metabolism phenotypes | 4      | 1            | 4                           |
| Miscellaneous phenotypes               | 9      | 7            | 9                           |

**Enriched Genomic vocabulary contributes towards a more comprehensive coverage list**

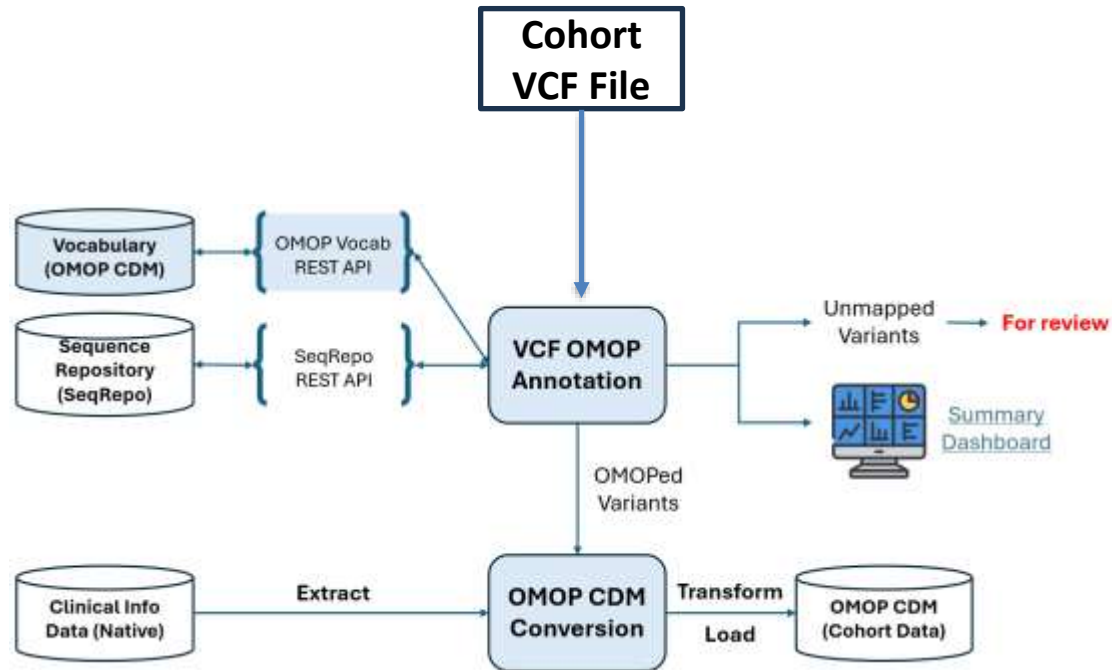


<https://github.com/biierwint/ODmapper>



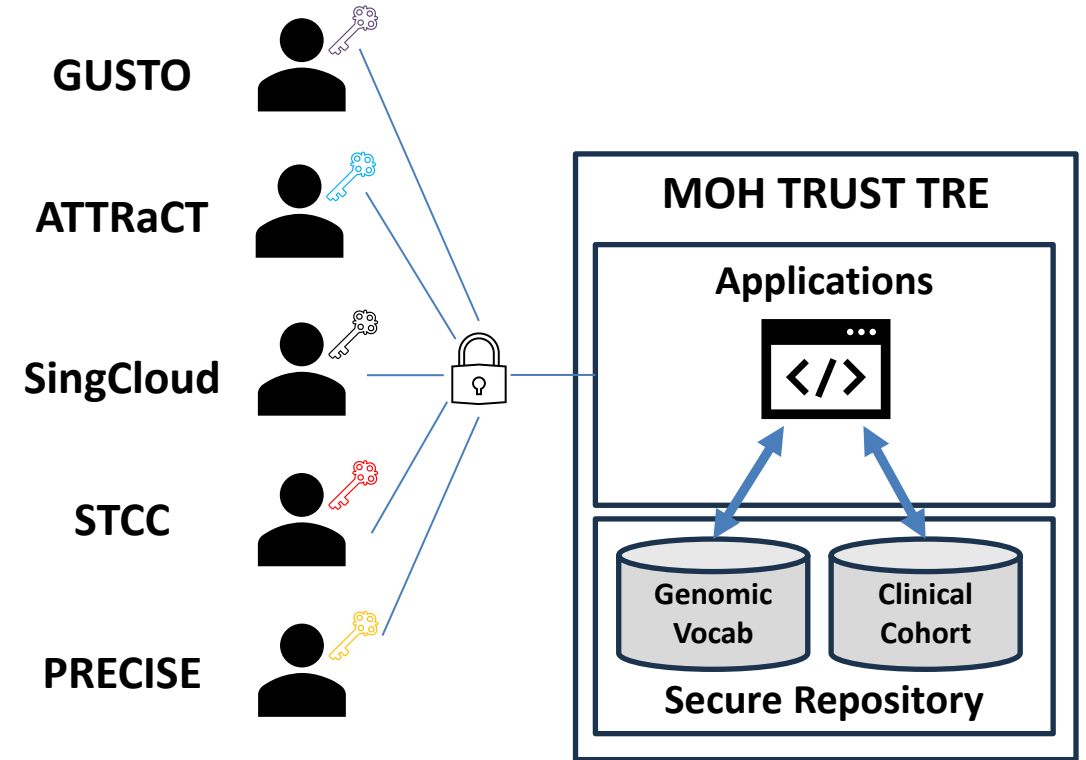
# Future Work

**First: Development of automated OMOP CDM converter for genomic data**



The cohort VCF file will be annotated with OMOP concept\_id based on enriched genomic vocabulary. The OMOPed variants will be converted to OMOP CDM (v5.4)

**Second: Deployment of application on the MOH-TRUST TRE (enTRUST)**



MOH TRUST TRE as the central TRE to host the OMOP CDM enriched genomic vocabulary and sensitive clinical cohorts which can only be accessible by the trusted users.



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- Dr. Low Pin Yan
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- **OHDSI Team**

- Dr. Anna Ostropolets
- Dr. Christian Reich
- Mr. Laurence Lawrence-Archer (Odysseus Inc.)





# Asian and/or Pacific Islander: Unmasking health disparities within commonly aggregated diverse populations in the US Department of Veterans Affairs (VA)

Benjamin Viernes<sup>1,3</sup>, Scott L DuVall<sup>1,2</sup>, Patrick R Alba<sup>1,2</sup>, Qiwei Gan<sup>1,2</sup>, Elizabeth E Hanchrow<sup>1</sup>, Mengke Hu<sup>1,2</sup>, Gregorio Coronado<sup>1,3</sup>, Andy Subica, Curtis Lowery<sup>3</sup>, Scott Hofer<sup>3,4</sup>, Vicki Shambaugh<sup>3,4</sup>, Kalani Raphael<sup>1-3</sup>

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3 – Center for Pacific Islander Veterans Health. VA Pacific Islands Healthcare System. Honolulu, HI, USA

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# United States' Government Office of Management and Budget (OMB) Race Categories

- 1977 Directive 15: Asian or Pacific Islander (API)
- 1997 Statistical Policy Directive 15: First step towards disaggregating Asian or Pacific Islander to 2 distinct categories
  - Asian
  - Native Hawaiian or Pacific Islander (NHPI)
- 2024: API still used in many common data sources



# Failure to Recognize Pacific Islander Inequity

- Of 853,654 VA Patients identified as API, 180,804 can be identified by the more granular NHPI
- NHPI that can be disaggregated are different than the aggregate API category.

|                                     | API             | NHPI            |
|-------------------------------------|-----------------|-----------------|
| <b>VA Patients</b>                  | 853,654         | 180,804         |
| <b>Mean Age</b>                     | 52.74           | 60.91           |
| <b>Sex = Male - N (%)</b>           | 746,646 (87.5%) | 158,663 (87.8%) |
| <b>Mean Years of VA Observation</b> | 12.3            | 13.6            |
| <b>Mean Measurement Count</b>       | 224.5           | 316.5           |
| <b>Mean Diagnosis Count</b>         | 1097            | 1614            |
| <b>Mean VA Interaction Count</b>    | 175             | 236             |



# Masking Health Disparities

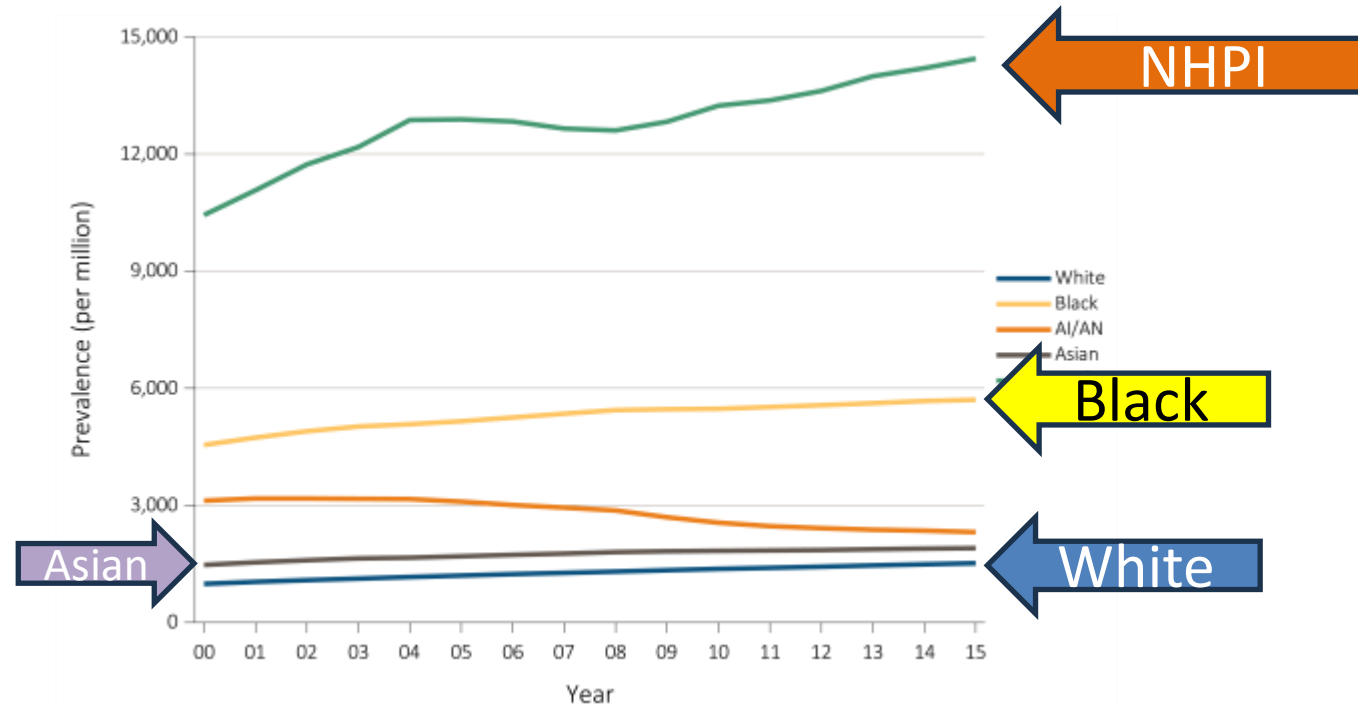
- Disaggregated from API, NHPI exhibit higher proportions with cardio-metabolic diseases
- Disaggregation of NHPI demonstrates the need to enforce disaggregated collection of race and ethnicity data

|                                 | API             | NHPI           | Polynesian     | Micronesian   | Melanesian  |
|---------------------------------|-----------------|----------------|----------------|---------------|-------------|
| VA Patients                     | 853,654         | 180,804        | 48,890         | 17,864        | 2,383       |
| NHPI-related Conditions - N (%) |                 |                |                |               |             |
| Chronic Kidney Disease          | 106,797 (12.5%) | 43,186 (23.9%) | 14,647 (30.0%) | 4,277 (23.9%) | 263 (11.0%) |
| Cardiovascular Disease          | 118,816 (13.9%) | 51,887 (28.7%) | 14,635 (29.9%) | 4,139 (23.2%) | 269 (11.3%) |
| Diabetes Mellitus               | 185,285 (21.7%) | 66,285 (36.7%) | 21,092 (43.1%) | 6,282 (35.2%) | 440 (18.5%) |



# NHPI in 2017 US Renal Data Systems Report

- Prevalence of ESRD in 2017

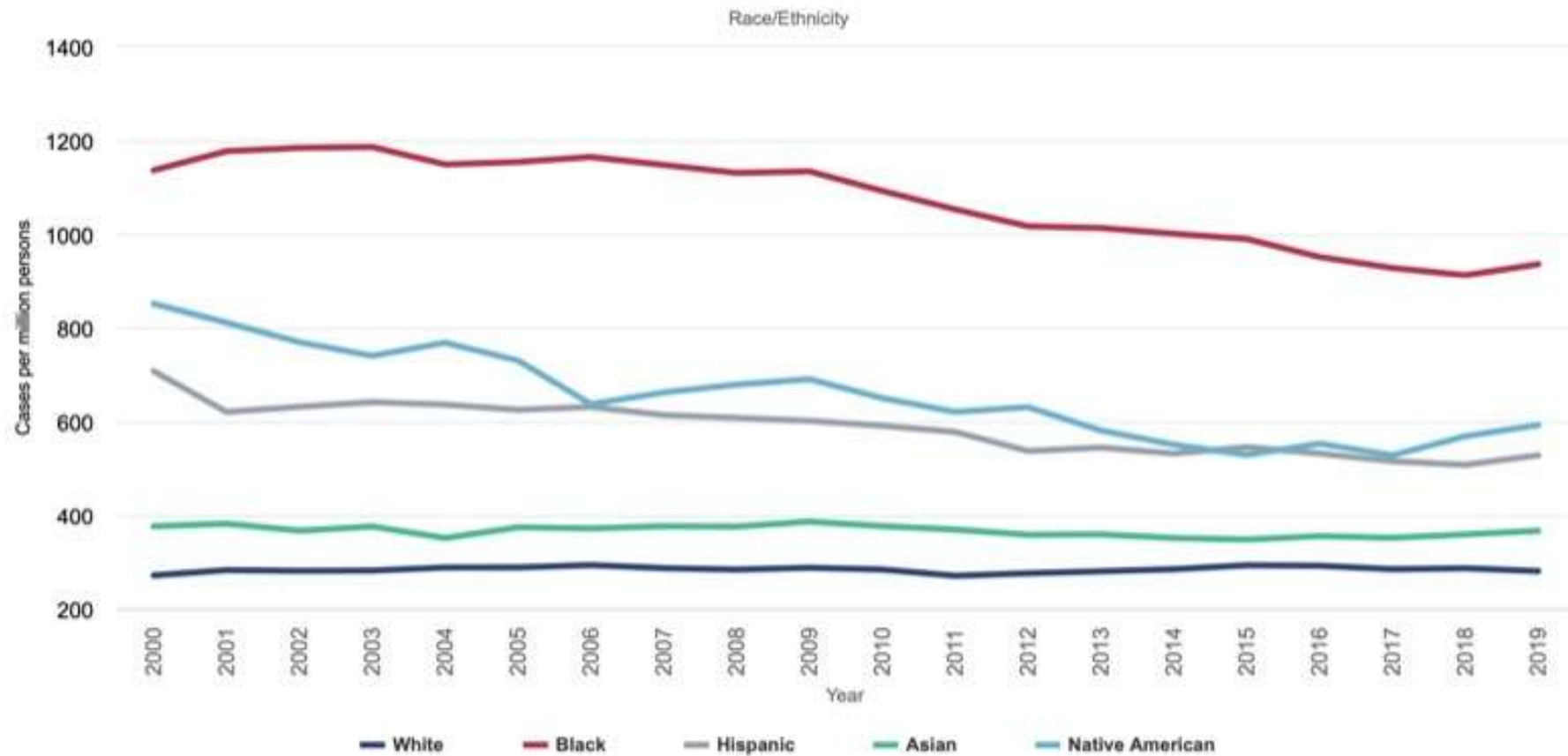


Data Source: Reference Table B.2(2) and special analyses, USRDS ESRD Database. Point prevalence on December 31 of each year. Standardized for age and sex. The standard population was the U.S. population in 2011. Abbreviations NH/PI: Native Hawaiian/Pacific Islander; AI/AN: Americans Indian/Alaska Natives; ESRD, end-stage renal disease.



# NHPI invisible in 2021

- NHPI absent from USRDS reports of Kidney failure in the US by race & ethnicity



Data Source: 2021 United States Renal Data System Annual Data Report



# Applying the OMOP Common Data Model to Facilitate Benefit-Risk Assessments of Medicinal Products Using Real-World Data from Singapore and South Korea

Hui Xing Tan, Desmond Chun Hwee Teo, Dongyun Lee, Chungsoo Kim, Jing Wei Neo, Cynthia Sung,  
Haroun Chahed, Pei San Ang, Doreen Su Yin Tan, Rae Woong Park, Sreemanee Raaj Dorajoo

Vigilance & Compliance Branch, Health Products Regulation Group, Health Sciences Authority, Singapore  
Department of Biomedical Informatics, Ajou University School of Medicine, Suwon, Korea  
Department of Biomedical Sciences, Graduate School of Medicine, Ajou University, Suwon, Korea  
Health Services and Systems Research, Duke-NUS Medical School, Singapore  
Department of Pharmacy, Khoo Teck Puat Hospital, Singapore



# Agenda

- Background
- Objectives
- Methods
- Results
- Discussion
- Conclusion





# Background

- Regulators need to monitor the effectiveness, safety, and utilization of health products in routine care
- There is increasing interest among regulators in using real-world data (RWD) to enhance their understanding of the benefits and risks of health products
- However, analysing RWD (typically from healthcare databases) and generating real-world evidence (RWE) to fulfil this can be challenging



# Objectives

- Characterise the benefits of converting Electronic Medical Records (EMRs) to a common data model (CDM)
- Assess the potential of CDM-converted data to rapidly generate insights for benefit-risk assessments in post-market regulatory evaluations and decisions



# Methods

Two phases:

1. Carry out conversion of Electronic Medical Record (EMR) data from their source files to the OMOP-CDM
2. Simulate an illustrative benefit-risk assessment of the converted data using available tools and code sets



# Methods

## The data:

|                 | Singapore  | South Korea   |
|-----------------|--|---|
| Data source     | EMR data from a tertiary acute care hospital in Singapore which provides a wide range of medical and surgical specialty services | EMR data from a 1,200-bed tertiary care facility in South Korea providing medical and surgical specialty services |
| Population size | 260,000 unique patients  | 2,700,000 unique patients   |
| Period of data  | Jan 2013 – Dec 2016  | Jan 1994 – Dec 2020   |



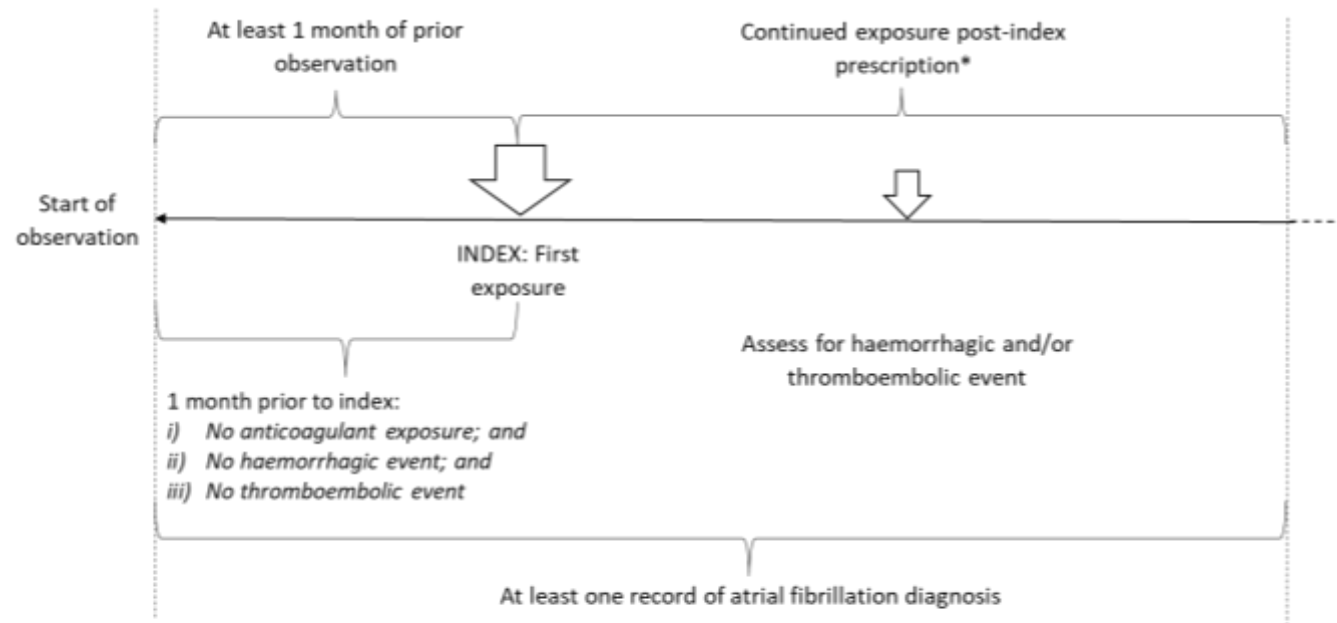
# Methods

- Conversion of Singapore source data to OMOP-CDM version 5.3.0
  - **Used “Rabbit-In-a-Hat” software**
  - Vocabulary mappings were applied to translate the codes and values used in the source data to those used in the CDM.
    - Diagnosis codes: ICD-9, ICD-10 → SNOMED-CT
    - **Drugs: RxNorm Extension**
    - Laboratory tests and vitals measurements: Logical Observation Identifiers Names and Codes (LOINC)



# Methods

- Illustrative Analysis following CDM Conversion
  - Patients with newly diagnosed **atrial fibrillation (AF)** who were newly started on **oral anticoagulants (OAC)**.
  - Patients were followed up for the occurrence of **bleeding (safety)** or **thromboembolic events (effectiveness)** at any time after the first OAC exposure.



\*At minimum, one prescription for an oral anticoagulant within a 3-month window



# Methods

- Illustrative Analysis following CDM Conversion
  - Produced bar charts to visualize drug utilization and effectiveness and safety event proportions to facilitate multiple comparisons in benefit-risk assessments.
  - External validation on EMR data from Ajou University Medical Center (AUMC) in South Korea was performed
    - to illustrate the potential of generating comparable results from different geographical cohorts of patients, and
    - to assess whether any signal of observable differences between agents persisted across different cohorts.



# Results

## Conversion of Singapore source Data to OMOP-CDM version 5.3.0

Quantity and structure of data imported from a tertiary acute care hospital in Singapore from January 2013 to December 2016

| OMOP-CDM table       |                           | Source table                            |                           |                         |
|----------------------|---------------------------|---|---------------------------|-------------------------|
| Table name           | Number of rows of records | Table name                              | Number of rows of records | Proportion migrated (%) |
| person               | 245,561                   | t_demographics                          | 258,038                   | 95.2                    |
| condition_occurrence | (primary) 210,830         | t_primary_diagnosis                     | 222,554                   | 94.7                    |
|                      | (secondary) 799,169       | t_secondary_diagnosis                   | 839,265                   | 95.2                    |
| measurement          | 14,116,544                | t_lab_result                            | 15,523,576                | 90.9                    |
| visit_occurrence     | 1,041,587                 | t_encounter                             | 1,057,263                 | 98.5                    |
| drug_exposure        | 4,378,657                 | t_eprescription_dispersing <sup>a</sup> | 2,147,505                 | 84.8                    |
|                      |                           | t_inpatient_med_order <sup>b</sup>      | 3,015,159                 | 84.8                    |

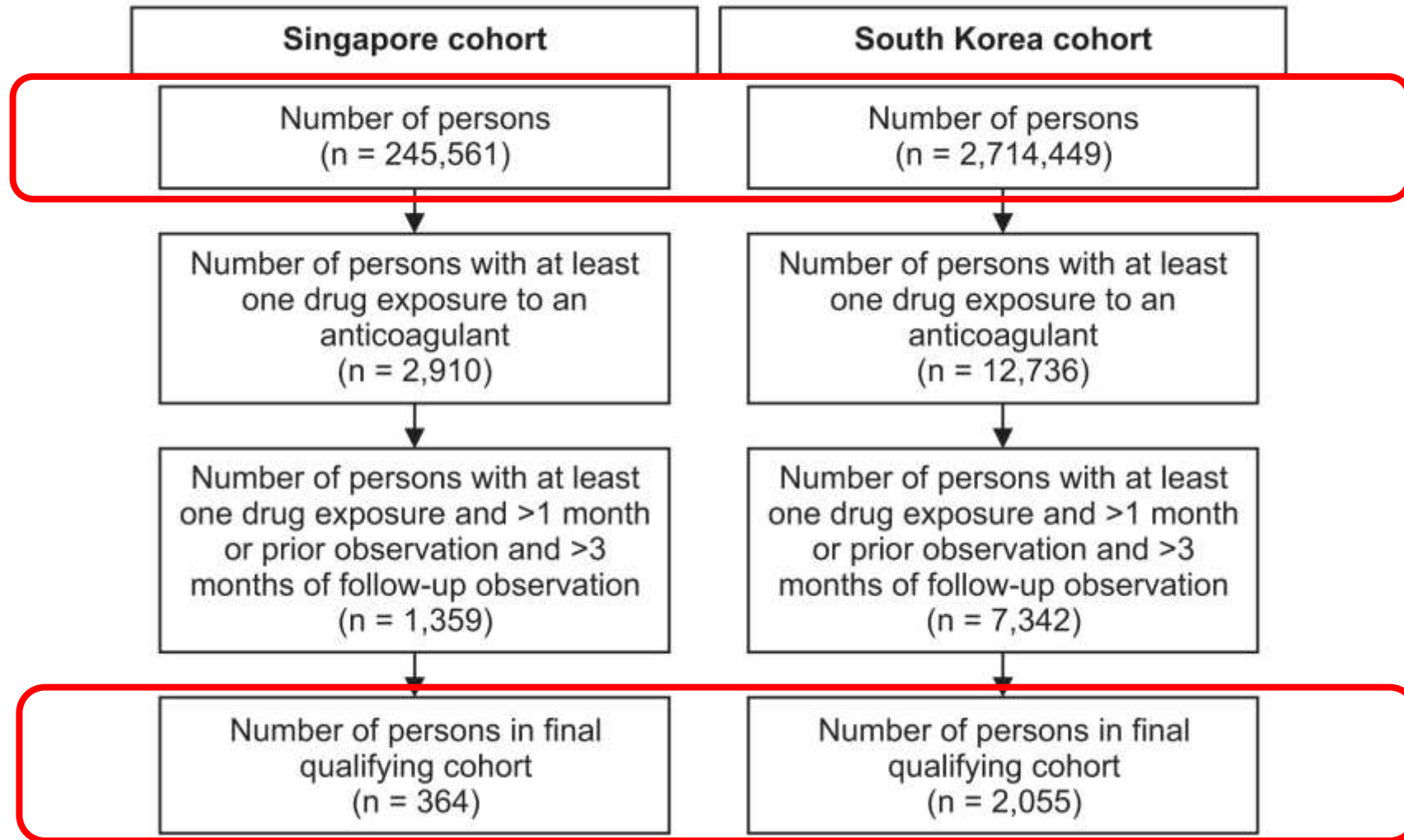
<sup>a</sup>Refers to outpatient pharmacy orders and inpatient discharge prescriptions.

<sup>b</sup>Refers to medications used during inpatient ward stay.





# Results



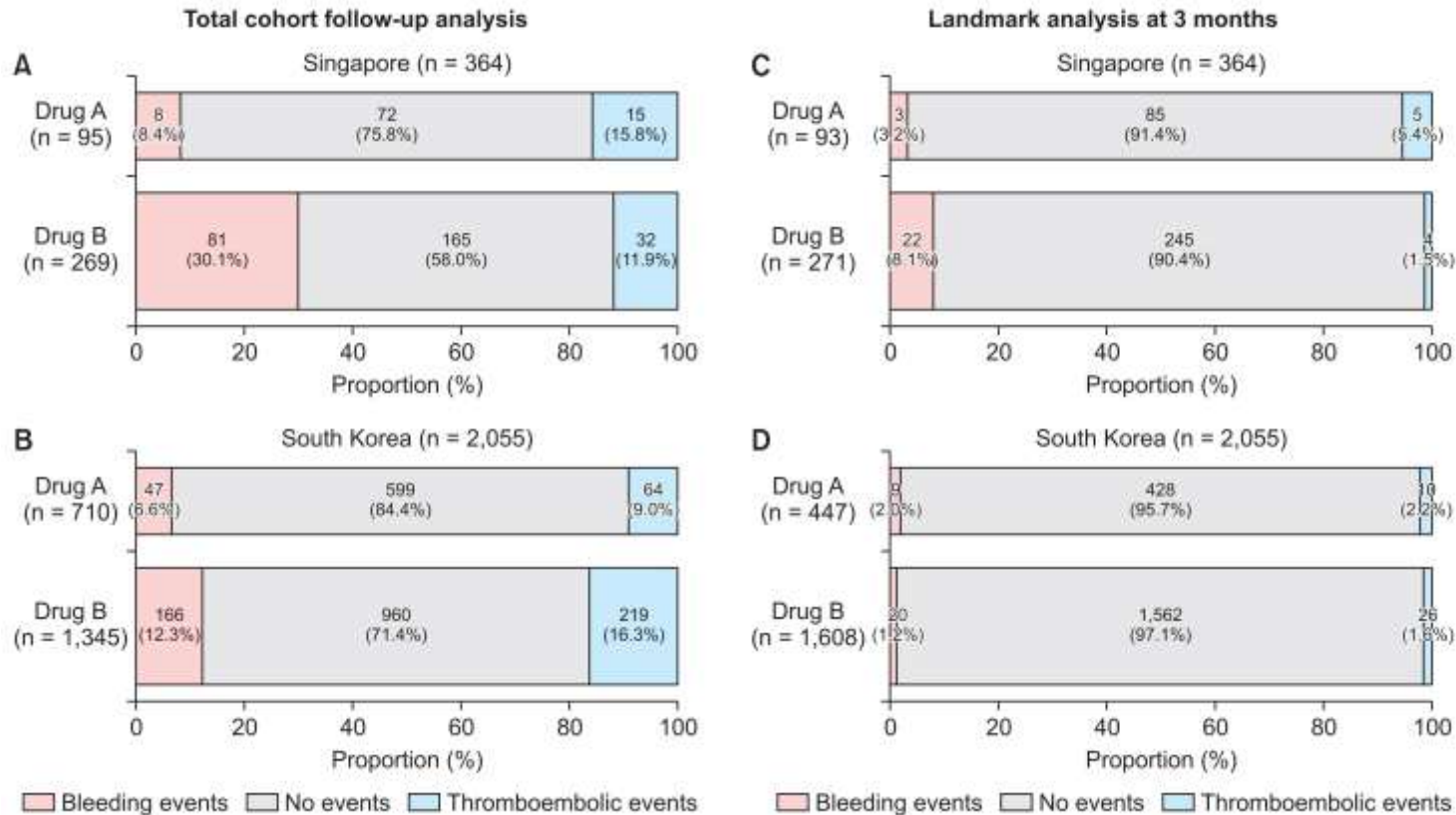


# Results

Table 2. Baseline characteristics of the final cohorts from Singapore and South Korea

|                            | Warfarin   |              | Rivaroxaban |             | Combined   |              | <i>p</i> -value <sup>d</sup> |
|----------------------------|------------|--------------|-------------|-------------|------------|--------------|------------------------------|
|                            | Singapore  | South Korea  | Singapore   | South Korea | Singapore  | South Korea  |                              |
| Number of patients         | 269 (73.9) | 1,345 (65.5) | 95 (26.1)   | 710 (34.5)  | 364 (100)  | 2,055 (100)  |                              |
| Age (yr)                   | 70 (15)    | 63 (17)      | 71 (15)     | 69 (14)     | 72 (15)    | 66 (17)      | <0.001                       |
| Sex                        |            |              |             |             |            |              | <0.001                       |
| Male                       | 142 (52.7) | 854 (63.5)   | 44 (46.3)   | 398 (56.1)  | 186 (51.1) | 1,252 (60.9) |                              |
| Female                     | 127 (47.2) | 491 (36.5)   | 51 (53.7)   | 312 (43.9)  | 178 (48.9) | 803 (39.1)   |                              |
| Race                       |            |              |             |             |            |              | <0.001                       |
| Korean                     | NA         | 1,345 (100)  | NA          | 710 (100)   | NA         | 2,055 (100)  |                              |
| Chinese                    | 163 (60.6) | NA           | 66 (69.5)   | NA          | 229 (62.9) | NA           |                              |
| Malay                      | 66 (24.5)  | NA           | 20 (21.1)   | NA          | 86 (23.6)  | NA           |                              |
| Indian                     | 20 (7.4)   | NA           | 5 (5.3)     | NA          | 25 (6.9)   | NA           |                              |
| Others                     | 20 (7.4)   | NA           | 4 (4.2)     | NA          | 24 (6.6)   | NA           |                              |
| Event outcome <sup>a</sup> |            |              |             |             |            |              | <0.001                       |
| Bleeding                   | 81 (30.1)  | 166 (12.3)   | 8 (8.4)     | 47 (6.6)    | 89 (24.5)  | 213 (10.4)   |                              |
| Thromboembolic             | 32 (11.9)  | 219 (16.3)   | 15 (15.8)   | 64 (9.0)    | 47 (12.9)  | 283 (13.8)   |                              |
| Neither                    | 156 (58.0) | 960 (71.4)   | 72 (75.8)   | 599 (84.4)  | 228 (62.6) | 1,559 (75.9) |                              |

# Results



Drug A: rivaroxaban. Drug B: warfarin

Denominator for percentages: number of patients in the cohort on the drug

Numerator for percentages: number of patients in the cohort on the drug who experienced the event (pink/blue), or were event free (grey)

- Initially, rivaroxaban appears to be the preferred agent (left) with fewer bleeding and thromboembolic events
- However, the benefit-risk ratios are similar after adjusting for observation time (right)



# Discussion

- CDM conversion alters only the form, but not the substance of the data
  - need to understand the provenance and processes that generated the data
- Conversion can speed up analyses
- Modifications and extensions to previously written code likely required for specific use cases
- Proposed bar graphs remain an unadjusted descriptive analysis of the rate of events in different populations exposed to comparator agents
- Incorporating methods to adjust for confounders and visualize the adjusted event rates would be important areas of future research



# Conclusion

- While the structure of the OMOP-CDM and its accessory tools facilitate real-world data analysis, extending them to fulfil regulatory analytic purposes in the post-market setting, such as benefit-risk assessments, may require layering on additional analytic tools and visualisation techniques



*Thank you*

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# Explore the opinions and attitudes of the application of common data models in regional databases from the perspective of the Chinese population

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Yexian Yu

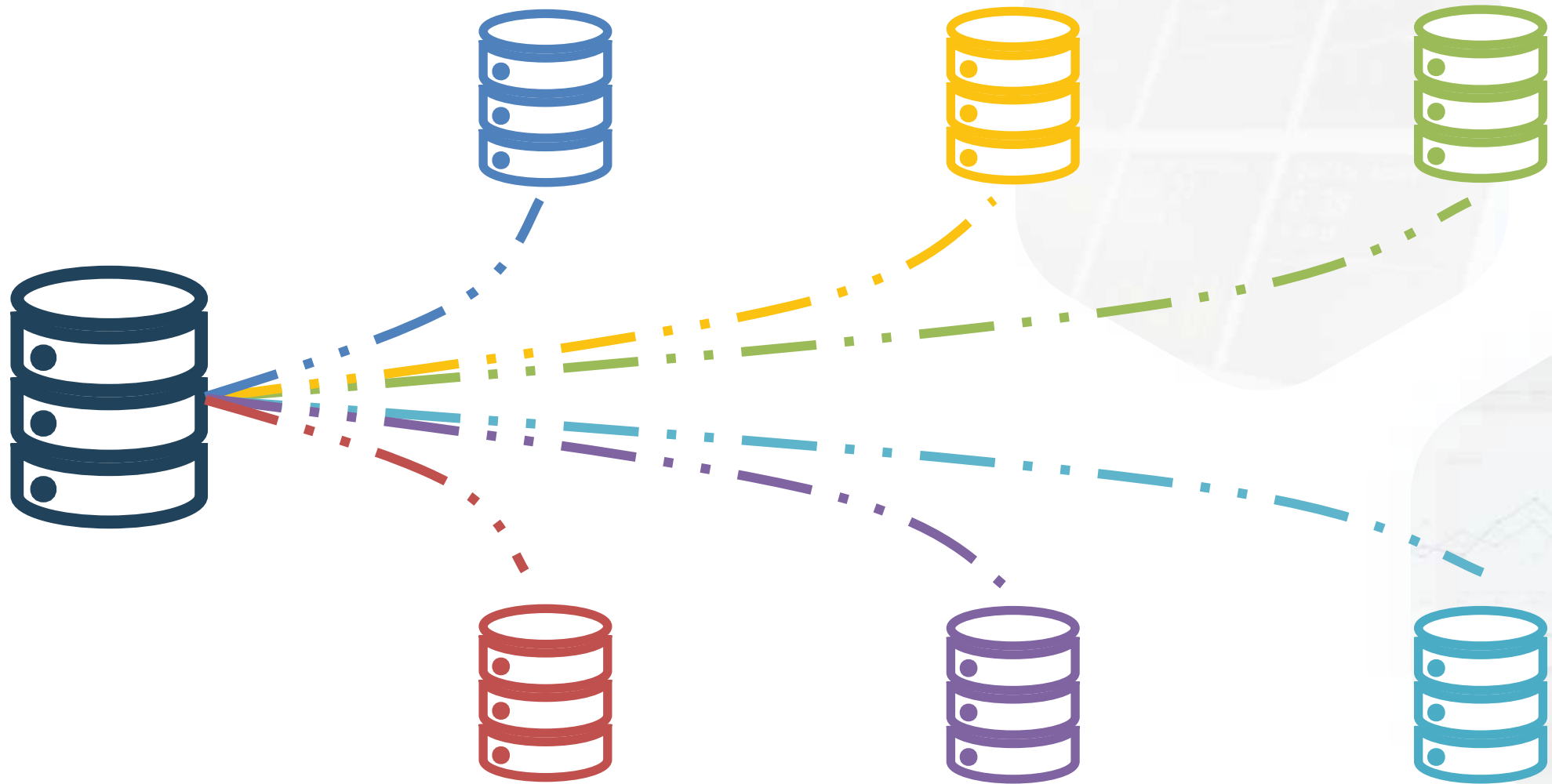
Hainan University, China

Hainan Lecheng Institute of Real World Research, China

Department of Epidemiology and Biostatistics, School of Public Health, Peking University, China



# Background



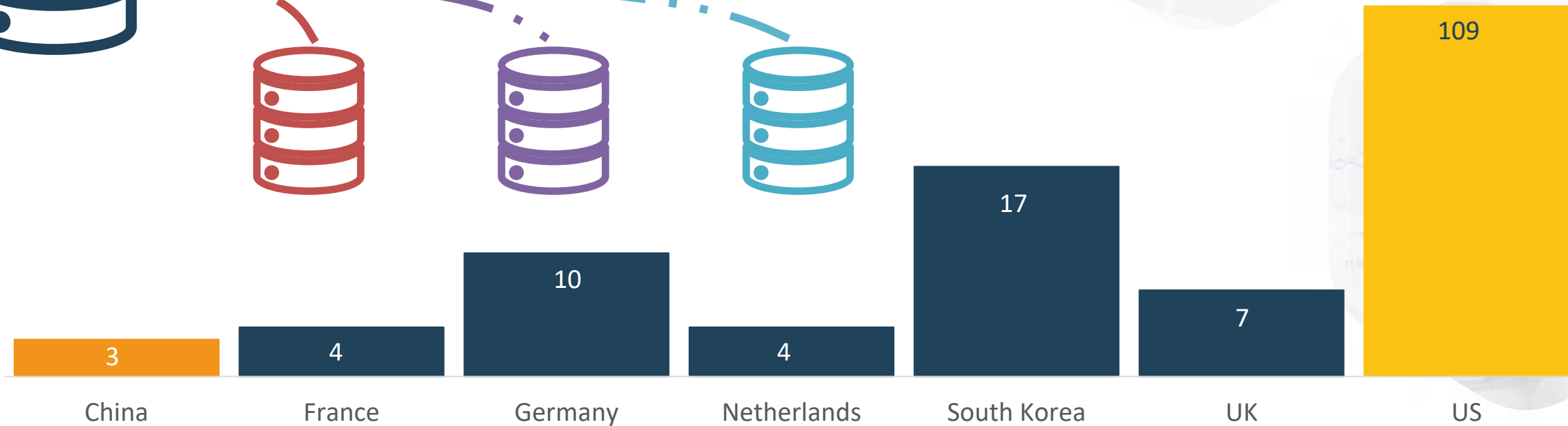




# Background



- The application of CDM in China is **relatively low**, which may be related to a lack of understanding and recognition of CDM<sup>1</sup>.





# Background

# WHY IS THAT?!



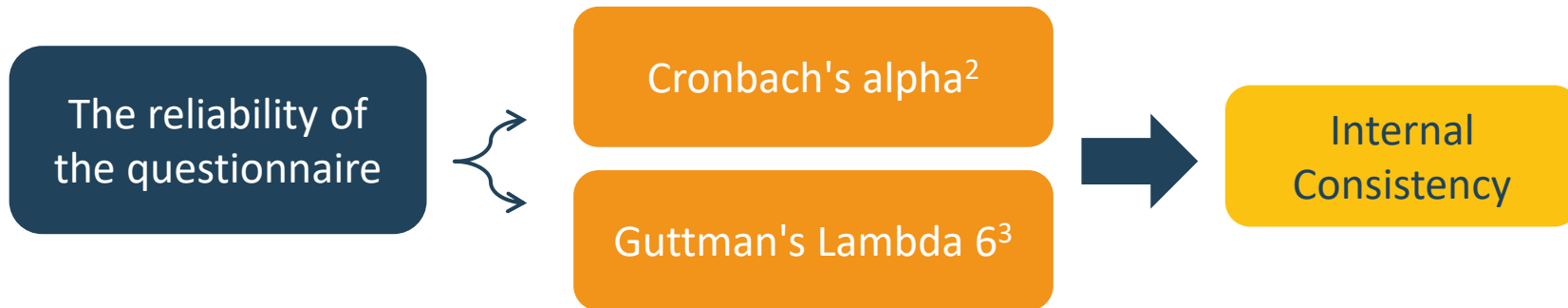


# Questionnaire Design



## Questionnaire Items

|                       |                      |                         |
|-----------------------|----------------------|-------------------------|
| Gender                | CDM Awareness        | OMOP Awareness Source   |
| Age                   | CDM Awareness Source | OMOP Mainstream Ability |
| Working/studying Area | CDM Necessity        | OMOP Benefits           |
| Occupation            | CDM Type             | OMOP Challenges         |
| Education Level       | OMOP Awareness       | Suggestions             |





# Survey results

200 Responses

From 18<sup>th</sup> September 2024 to 22<sup>nd</sup> September 2024

Cronbach's alpha

0.96

Guttman's Lambda 6

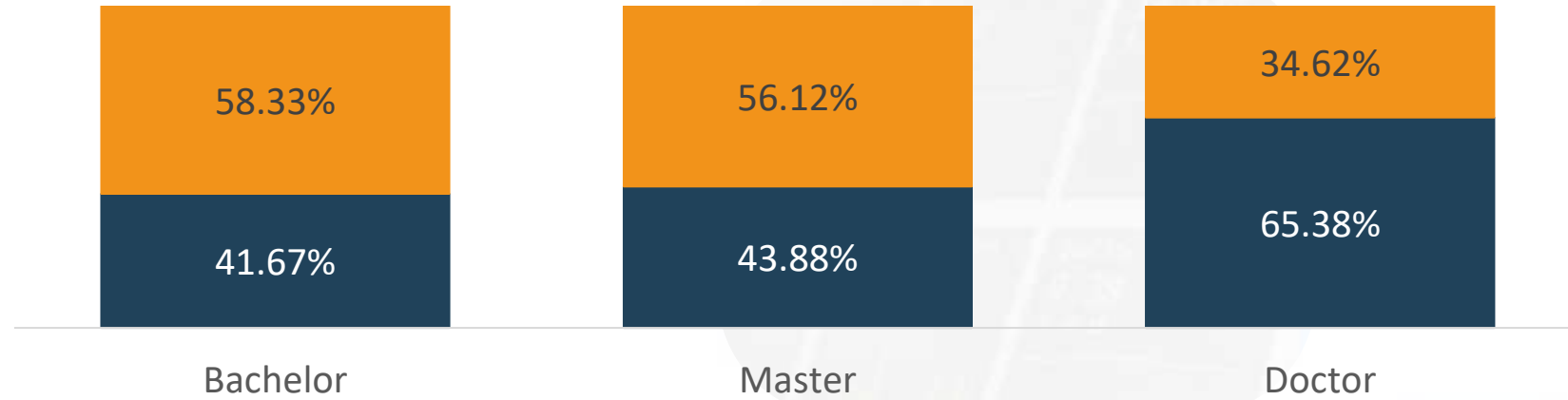
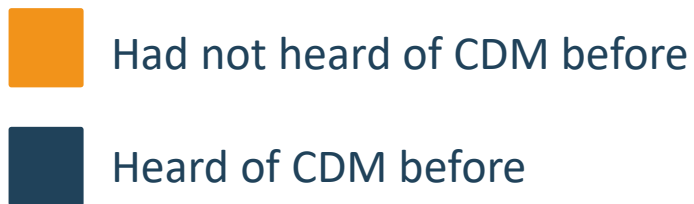
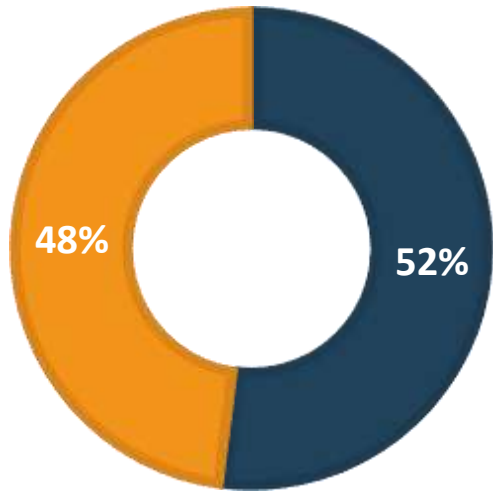
0.98



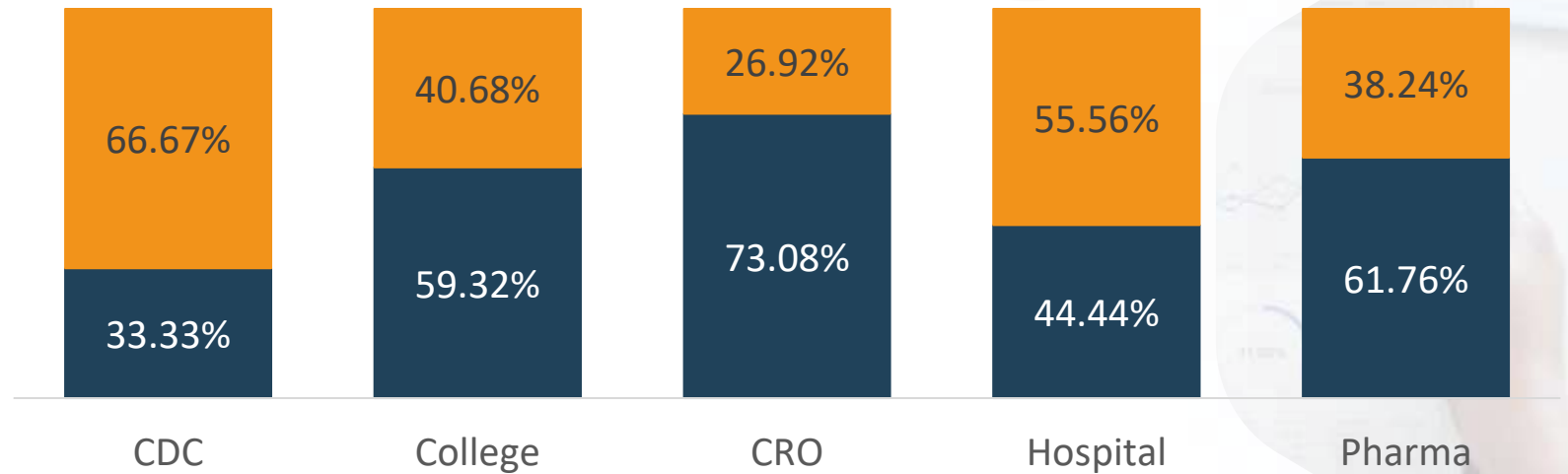
high internal consistency and strong inter-item correlations within the questionnaire



# Survey results



$$\chi^2 = 8.320, P = 0.004$$

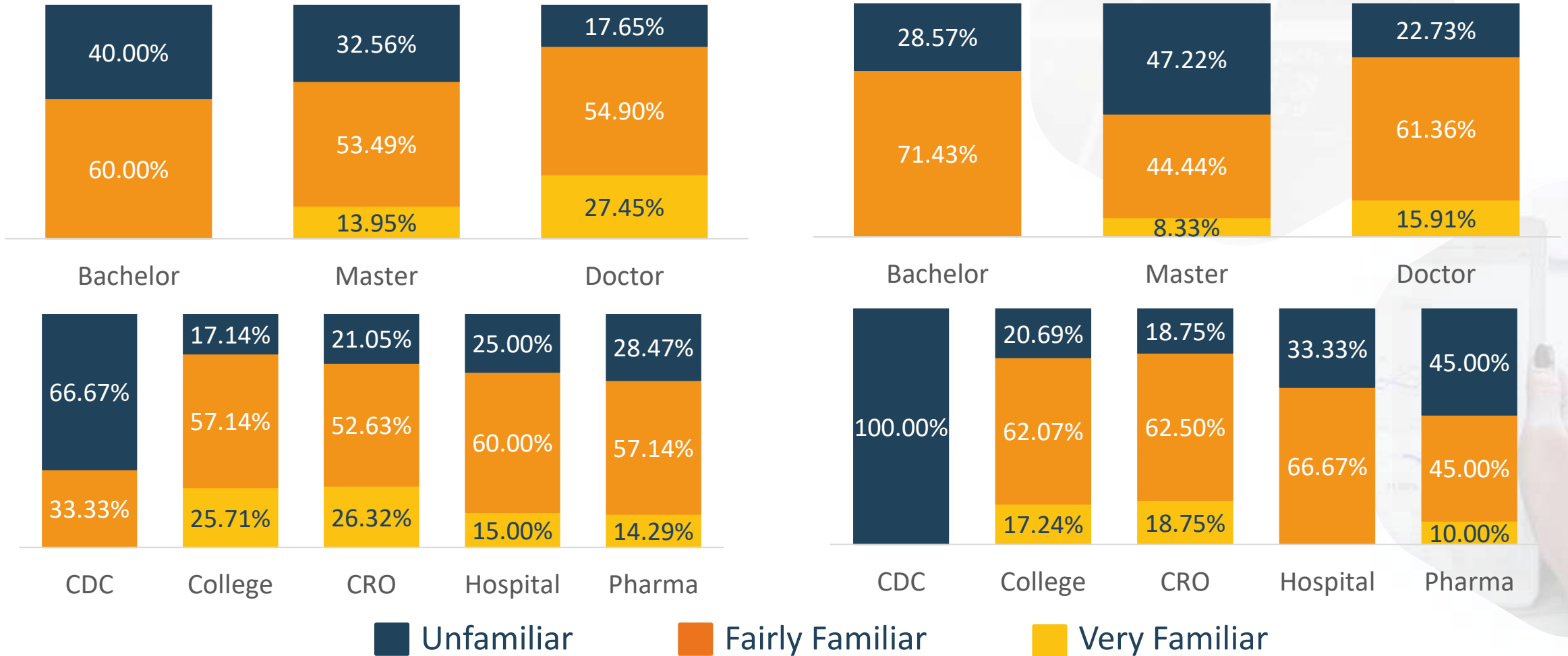


$$\chi^2 = 9.950, P = 0.041$$

# Survey results

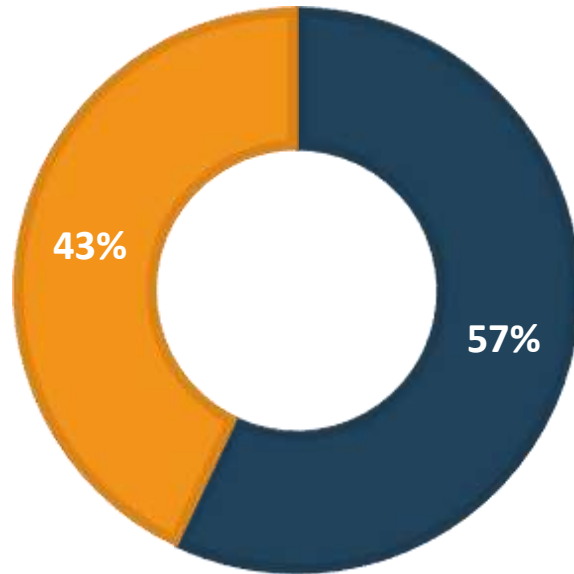
CDM

OMOP





# Survey results



- **More than half** of the participants believe that OMOP could become the mainstream choice for CDM in Chinese regional databases.

## benefits

- Enhance the operability and comparability of data in Chinese regional databases
- Facilitate the sharing, comparison, and integration of data from different sources.
- Help drive innovation and progress in the research field

## Challenges

- There are barriers between different data sources
- Mapping requires a significant amount of manual work, time, and cost
- Some China-specific information cannot be matched to standard concept IDs



# Participants' suggestions

Establishing a reasonable data-sharing mechanism at the national level



Establishing small-scale OMOP disease-specific databases



Involving professionals from diverse backgrounds



Introduction of artificial Intelligence



Enhancing education and promotion of CDM



Ensuring information encryption and data security







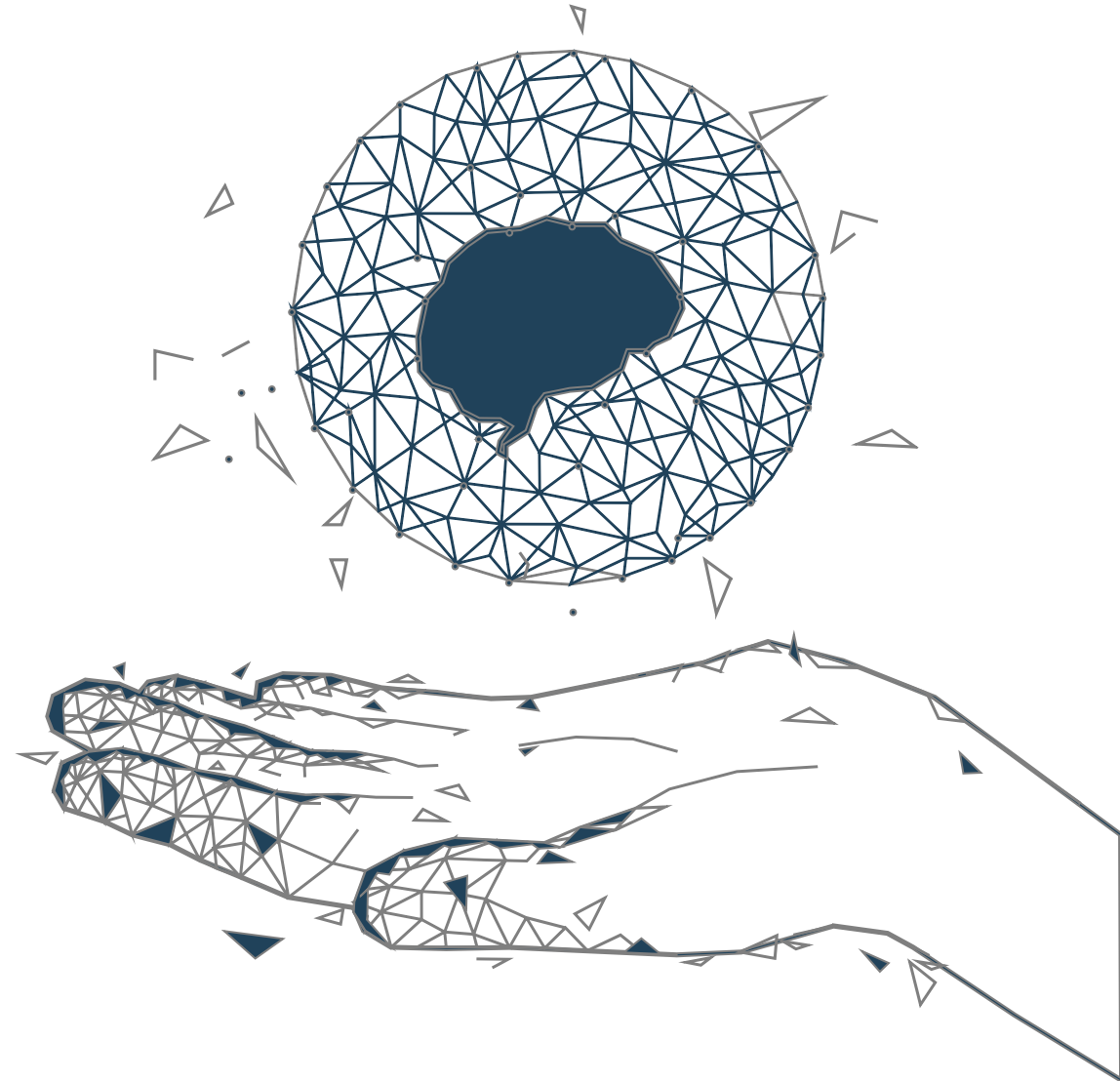
# Conclusions



Based on the statistical analysis of the questionnaire results, participants generally hold a **positive attitude** towards the application of CDM in regional databases in China.



# Thanks



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