

# Comparing Database Harmonisation Methods Applied to Real-World Electronic Healthcare Data

**First published:** 29/03/2023

**Last updated:** 23/04/2024

Study

Planned

## Administrative details

### EU PAS number

EUPAS104219

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### Study ID

104220


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### DARWIN EU® study

No

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### Study countries

 United Kingdom

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### Study description

The use of multiple health databases is the preferred method for generating evidence on the safety and effectiveness of medicines, compared to the use of a single database. However, these larger studies have an additional number of complexities. These are in part due to the heterogeneity amongst data sources, a challenge only amplified when using internationally distributed databases. Harmonisation methods such as the use of a common protocol (CP) and/or a common data model (CDM) can improve consistency of findings across databases. Here we will compare different harmonisation methods by comparing the subsequent effect estimates and summary measures in an applied internationally distributed database setting.

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## Study status

Planned

## Research institutions and networks

### Institutions

Division of Pharmacoepidemiology & Clinical Pharmacology (PECP), Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University

 Netherlands

**First published:** 01/03/2010

**Last updated:** 27/05/2026

Institution

Educational Institution

ENCePP partner

## Contact details

### **Study institution contact**

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Study contact

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### **Primary lead investigator**

Nicholas Hunt

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 01/09/2019

Actual: 01/09/2019

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### **Study start date**

Planned: 01/06/2023

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### **Date of final study report**

Planned: 01/10/2023

## Sources of funding

- Other

## More details on funding

PhD project

## Regulatory

## Was the study required by a regulatory body?

No

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## Is the study required by a Risk Management Plan (RMP)?

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

#### **Main study objective:**

The objective is to assess whether the implementation of a study specific CDM and a general CDM, versus using a common protocol alone has an impact on the consistency of the study results of a pharmacoepidemiologic study in real-world data.

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

## **Anatomical Therapeutic Chemical (ATC) code**

(B01AA) Vitamin K antagonists

Vitamin K antagonists

(B01AE07) dabigatran etexilate

dabigatran etexilate

(B01AF) Direct factor Xa inhibitors

Direct factor Xa inhibitors

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## **Medical condition to be studied**

Haemorrhage

Ischaemic stroke

Acute myocardial infarction

Glaucoma

## **Population studied**

### **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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### **Estimated number of subjects**

44000

## **Study design details**

## Outcomes

TBC, TBC

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## Data analysis plan

TBC

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data source(s)

Clinical Practice Research Datalink

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### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No