Comparative effectiveness and safety studies using the target trial emulation and estimand frameworks (TARGET-EU)

First published: 10/04/2025

Last updated: 10/04/2025

Study Planned

Administrative details

EU PAS number

EUPAS1000000539

Study ID

1000000539

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] Denmark
- [ ] Finland
- [ ] Italy

☐ Netherlands

☐ Norway

☐ Spain

☐ United Kingdom

Study description

This project, entitled Comparative Effectiveness and Safety Studies Using the Target Trial Emulation and Estimand Frameworks (TARGET EU), aims to advance regulatory use of real-world data (RWD) through application of target trial emulation (TTE) and estimand methodologies.

The overarching goal is to generate evidence that bridges randomized controlled trials (RCTs) and observational studies, supporting regulatory decisions where RCTs are infeasible.

TARGET EU comprises four objectives:

(1) to review and assess the integration of TTE with the estimand framework for evaluating drug effectiveness and safety,

(2) to characterise the suitability of diverse European RWD sources for TTE,

(3) to identify regulatory scenarios—such as PASS, PAES, and trials with external comparators—where TTE provides value, and

(4) to establish good practice guidelines for communicating TTE results to regulators.

To achieve these aims, the consortium will conduct a literature review and regulatory landscape analysis; assess data quality, accessibility, and fitness-for-purpose using a structured framework; and implement ten emulated trials using rich datasets from the Netherlands, Spain, and the UK, with expansion to other EU countries.

These case studies span public health priorities, including COVID-19 vaccine effectiveness and comparative oncology drug safety.

Study status

Planned

Research institutions and networks

Institutions

Electronic Health Records (EHR) Research Group, London School of Hygiene & Tropical Medicine (LSHTM)

United Kingdom

First published: 19/04/2010

Last updated: 30/10/2024

Institution | Educational Institution | ENCePP partner

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

Netherlands

First published: 01/03/2010

Last updated: 23/05/2024

Institution | Educational Institution | ENCePP partner

Clinical Pharmacology, Vall d'Hebron Institut de Recerca (VHIR)

Spain

First published: 18/05/2021

Last updated: 20/05/2021

Institution | Hospital/Clinic/Other health care facility | ENCePP partner

University Medical Center Utrecht (UMCU)

Netherlands

First published: 24/11/2021

Last updated: 22/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Pharmacology Unit - Veneto Pharmacovigilance Centre (Pharmacol UNIVR), University Hospital Verona

Italy

First published: 25/10/2022

Last updated: 13/03/2025

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain

First published: 05/10/2012

Last updated: 23/05/2025

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Agenzia regionale di sanità della Toscana (ARS)

Italy

First published: 01/02/2024

Last updated: 12/03/2024

Institution | EU Institution/Body/Agency | ENCePP partner

Agencia Española de Medicamentos y Productos Sanitarios (Spanish Agency for Medicines and Medical Devices, AEMPS)

Spain

First published: 01/02/2024

Last updated: 04/09/2024

Institution | EU Institution/Body/Agency | Not-for-profit | Regulatory Authority | ENCePP partner

Teamit Institute

☐ Spain

First published: 12/03/2024

Last updated: 12/03/2024

Institution | Other | ENCePP partner

Sint Antonius Hospital

Networks

Vaccine monitoring Collaboration for Europe (VAC4EU)

☐ Belgium
☐ Denmark
☐ Finland
☐ France
☐ Germany
☐ Italy
☐ Netherlands

☐ Norway

☐ Spain

☐ United Kingdom

First published: 22/09/2020

Last updated: 22/09/2020

Network | ENCePP partner

EU Pharmacoepidemiology and Pharmacovigilance (PE&PV) Research Network

☐ Netherlands

First published: 01/02/2024

Last updated: 26/11/2024

Network

Contact details

Study institution contact

Daniala Weir eupepv@uu.nl

Study contact

eupepv@uu.nl

Primary lead investigator

Olaf Klungel

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 19/09/2024

Study start date
Planned: 10/10/2024

Date of final study report
Planned: 10/06/2026

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No