

TARGET-EU: Feasibility assessment based on the Data Quality Framework for EU medicines regulation.

First published: 31/10/2025

Last updated: 08/06/2026

Study

Finalised

Administrative details

EU PAS number

EUPAS1000000791

Study ID


1000000791

DARWIN EU® study

No

Study countries

 Belgium

 Denmark


 Finland

 Greece

 Italy

 Netherlands

 Spain

 United Kingdom

Study description

This feasibility assessment is part of the broader project "Comparative effectiveness and safety studies using the target trial emulation and estimand frameworks (TARGET-EU)" (EUPAS1000000539), which aims to enhance the understanding of opportunities, limitations and challenges associated with using the target trial emulation (TTE) and estimand frameworks (EF) to design and conduct non-interventional studies (NIS) that support regulatory decision-making, using European real-world data (RWD) sources. Ten NIS with causal objectives to address comparative safety or effectiveness will be considered to develop this understanding. As the suitability and timeliness of the data sources used for conducting each of those studies are essential, a feasibility assessment will be performed. This protocol outlines a series of steps to assess the feasibility of conducting the studies within the TTE framework using the envisioned data sources.


Study status

Finalised

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: 27/05/2026

Institution

Educational Institution

ENCePP partner

Health Services Research and Pharmacoepidemiology Unit (HSRP Unit) FISABIO

 Spain

First published: 30/11/2023


Last updated: 30/11/2023

Institution

Other

ENCePP partner

Real-World Evidence Team, University of Eastern Finland (RWE team)

 Finland

First published: 20/12/2017

Last updated: 27/08/2024

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

Outdated

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

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

 Netherlands

First published: 07/01/2022

Last updated: 19/12/2025

Institution

Non-Pharmaceutical company

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

Department of Medicine/Laboratory of Hygiene and Environmental Protection, Democritus University of Thrace

 Greece

First published: 30/11/2022

Last updated: 05/12/2022

Institution

Educational Institution

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

Clinical Data Science (IKNL), Netherlands Comprehensive Cancer Organisation

 Netherlands

First published: 04/04/2023

Last updated: 04/04/2023

Institution

Not-for-profit

ENCePP partner

Agenzia regionale di sanità della Toscana (ARS Toscana)

 Italy

First published: 01/02/2024

Last updated: 23/03/2026

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; Ghent University;
University of Copenhagen (UCPH).


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

Outdated

ENCePP partner

EU Pharmacoepidemiology and Pharmacovigilance (PE&PV) Research Network


 Netherlands

First published: 01/02/2024

Last updated: 24/09/2025

Network

Pedianet network (So.Se.Te)

 Italy

First published: 23/10/2025

Last updated: 08/04/2026

Network

Contact details

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 19/09/2024

Study start date

Planned: 10/10/2024

Actual: 10/10/2024

Date of final study report

Planned: 12/05/2025

Actual: 12/05/2025

Sources of funding

- EMA

Study protocol

[TARGET-EU_Studyprotocol_Feasibility_HMA-EMA Catalogues.pdf](#) (1.13 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Not applicable

Scope of the study:

Method development or testing

Other

Main study objective:

Objective 1: To develop an overview of advantages and challenges of combining target trial emulation with the estimand framework for comparative efficacy and safety studies

Objective 2: To characterise which types of European RWD sources are suitable to be used in the context of TTE studies and key aspects that should be attended to in a feasibility assessment of data sources for running such a study

Objective 3: To establish criteria for suitable regulatory cases, including PAES, PASS and clinical trials with external controls, that would benefit from TTE approach

Objective 4: To develop good practices to aid in communication of the TTE studies for regulatory purposes

Study design details

Setting

The ten case studies in the proposal are going to utilise data sources, included in the EU PE&PV Consortium Framework Contract EMA/2020/46/TDA/L5.06, from the Netherlands, Spain, UK, Greece, Denmark, Italy, Finland, Belgium, Latvia and Norway.

Documents

Study results

[TARGET-EU_Deliverable 3 - Feasibility Assessment.pdf](#) (1.29 MB)

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