Bias after censoring concomitant users of test- and control medication when investigating long-term survival outcomes in observational studies of medication effects

First published: 30/10/2026

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Study Planned

Administrative details

EU PAS number

EUPAS1000001159

Study ID

1000001159

DARWIN EU® study

No

Study countries

Germany

Study description

Simulation study to estimate bias and compare methods to handle situations in active comparator studies investigating long-term survival outcomes, such as time-to-cancer-diagnosis, where the drug of interest and the active comparator drug are used concomitantly.

Study status

Planned

Research institutions and networks

Institutions

Pharmacoepidemiology Research, Federal Institute for Drugs and Medical Devices (BfArM)

Germany

First published: 02/06/2023

Last updated: 23/04/2024

Institution | Regulatory Authority | ENCePP partner

Networks

Real4Reg

Belgium

Denmark

Finland

Germany

Ireland

Portugal

First published: 01/02/2024

Last updated: 16/07/2026

Network

Contact details

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Primary lead investigator

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 01/01/2023

Study start date

Planned: 16/11/2026

Date of final study report
Planned: 31/12/2026

Sources of funding

- EU institutional research programme

More details on funding

HORIZON Europe

Study protocol

Simulation study protocol Bias censoring.pdf (134.37 KB)

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 topic:

Other

Study topic, other:

Methodology

Study type:

Not applicable

Scope of the study:

Method development or testing

Main study objective:

This simulation study aims to compare methods aiming to mitigate the bias from censoring concomitant users, namely variations of the landmarking method and inverse-probability-of-censoring weighting and a combination thereof.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10BK) Sodium-glucose co-transporter 2 (SGLT2) inhibitors

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(A10BH) Dipeptidyl peptidase 4 (DPP-4) inhibitors

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Medical condition to be studied

Colorectal cancer

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