

Brand-specific influenza vaccine effectiveness in the Nordic countries

First published: 21/02/2025

Last updated: 25/02/2025

Study

Finalised

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/1000000481>

EU PAS number

EUPAS1000000481

Study ID

1000000481

DARWIN EU® study

No

Study countries

Denmark

Finland

Sweden

Study description

Seasonal influenza is a major public health concern, particularly for older adults and high-risk individuals. While vaccination is the primary preventive measure, its effectiveness varies across seasons, virus subtypes, and populations. This study evaluates the brand-specific effectiveness of seasonal influenza vaccines during the 2024–2025 season in Denmark, Finland, and Sweden, leveraging Nordic health registries for near real-time, large-scale assessments. The study focuses on individuals aged 65 years and older and high-risk adults under 65, estimating IVE against laboratory-confirmed influenza, influenza-like illness, hospitalization, ICU admission, and mortality. The objective is to provide timely brand-specific IVE estimates to inform vaccination strategies.

A nationwide register-based matched cohort design is used, applying target trial emulation and additional methodologies such as test-negative case-control design, negative control outcome analyses, regression discontinuity, and prior event rate adjustments to enhance validity. A feasibility assessment confirms that Denmark and Finland provide comprehensive data, while Sweden has partial regional coverage. The assessment finds that Nordic health registries, combined with appropriate methodologies, provide a strong foundation for conducting timely brand-specific IVE studies to support vaccination policy and regulatory decision-making.

This study generates high-quality real-world evidence to guide public health strategies ahead of the 2025–2026 influenza season. By leveraging robust data infrastructure and advanced epidemiological methods, it strengthens evidence-based vaccine policy and preparedness for future influenza seasons.

Study status

Finalised

Research institutions and networks

Institutions

Department of Epidemiology Research, Statens Serum Institut

Denmark

First published: 16/03/2010

Last updated: 24/02/2012

Institution

EU Institution/Body/Agency

Laboratory/Research/Testing facility

ENCEPP partner

Data Analytic Center (DAC), Danish Medicine Agency

Denmark

First published: 17/04/2023

Last updated: 17/04/2023

Institution

EU Institution/Body/Agency

ENCEPP partner

Finnish Institute for Health and Welfare (THL)

Finland

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Educational Institution

Laboratory/Research/Testing facility

Contact details

Study institution contact

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Study contact

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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: 29/10/2024

Actual: 29/10/2024

Study start date

Planned: 01/11/2024

Actual: 01/11/2024

Date of final study report

Planned: 06/01/2025

Actual: 06/01/2025

Sources of funding

- EMA

Study protocol

[Brand-specific IVE in Nordic settings.pdf](#)(846.37 KB)

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Feasibility analysis

Main study objective:

To document the feasibility of conducting annual brand-specific seasonal influenza vaccine effectiveness studies in Denmark, Finland, and Sweden.

Study Design

Non-interventional study design

Other

Study drug and medical condition

Name of medicine

INFLUVAC TETRA

FLUCELVAX TETRA (--)-SUSPENSION FOR INJECTION

FLUAD TETRA (--)-SUSPENSION FOR INJECTION

Name of medicine, other

Vaxigrip Tetra, Efluelda Tetra

Documents

Study report

[Feasibility of IVE studies in Nordic settings.pdf](#)(1009.74 KB)

Data management

Data sources

Data source(s)

Terveydenhuollon hoitoilmoitusrekisteri (Finland Care Register for Health Care)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Danish Health Data Registries

Data source(s), other

The Danish Civil Registration System, The Danish vaccination register, The National patient registry, The Danish Microbiology Database, Finnish Population Information System, National Vaccination Register Finland, Register for Primary Health Care Visits Finland, National Infectious Diseases Register Finland, Special Reimbursement Register and Prescription Centre database Finland, Register of Social Assistance Finland, Finnish Intensive Care Consortium's Quality Register for Intensive Care, Swedish vaccination register, Regional vaccination data, Swedish national inpatient register, Register on Surveillance of Notifiable Communicable Diseases (Sminet)

Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

[Disease registry](#)

[Drug dispensing/prescription data](#)

[Drug registry](#)

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

[Laboratory tests and analyses](#)

[Population registry](#)

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