

# Brand-specific influenza vaccine effectiveness in the Nordic countries

**First published:** 21/02/2025

**Last updated:** 16/06/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000481

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### Study ID

1000000481

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### DARWIN EU® study

No

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### Study countries

 Denmark

 Finland

 Sweden

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### 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 influenza vaccine effectiveness (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 was 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.

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## **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**

**Outdated**

**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

Anders Hviid 0000-0002-7509-9127

Primary lead investigator

### ORCID number:

0000-0002-7509-9127

## Study timelines

### Date when funding contract was signed

Planned: 29/10/2024

Actual: 29/10/2024

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### Study start date

Planned: 01/11/2024

Actual: 01/11/2024

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### Date of interim report, if expected

Planned: 06/01/2025

Actual: 06/01/2025

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

Planned: 02/05/2025

Actual: 08/06/2025

## Sources of funding

- EMA

## Study protocol

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

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

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**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.

To provide timely estimates of brand-specific seasonal influenza VE against laboratory-confirmed and influenza-related outcomes for the 2024-2025 season.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

INFLUVAC TETRA

FLUCELVAX TETRA

FLUAD TETRA

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**Medicinal product name, other**

Vaxigrip Tetra, Efluelda Tetra

## Documents

### Study report

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

[Influenza VE in Nordic countries-estimates for the 2024-2025 season.pdf](#) (3.99 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.

## Data sources

### Data source(s)

Terveydenhuollon hoitoilmoitusrekisteri (Finland Care Register for Health Care)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Danish Health Data Registries

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### 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)

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### **Data sources (types)**

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

[Disease registry](#)

[Drug registry](#)

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

[Laboratory tests and analyses](#)

[Pharmacy dispensing records](#)

[Population registry](#)

## 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