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

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 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.

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Institution | Outdated | EU Institution/Body/Agency | Laboratory/Research/Testing facility | ENCePP partner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

Swedish Medical Products Agency

Contact details

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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 interim report, if expected

Planned: 06/01/2025

Actual: 06/01/2025

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

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.

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

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

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 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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No