

Exposure and coverage to routine schedule vaccines in different EU countries (ADVANCE-POC2)

First published: 02/02/2019

Last updated: 23/10/2025

Study

Planned

Administrative details

EU PAS number

EUPAS27851

Study ID

27852

DARWIN EU® study

No

Study countries

- ☐ Belgium
- ☐ Denmark
- ☐ Italy
- ☐ Netherlands

- ☐ Spain
 - ☐ Switzerland
 - ☐ United Kingdom
 - ☐ United States
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Study description

Rationale and Background: To increase readiness of European data sources to conduct multi-site vaccine coverage, benefit and risk studies
Research Question and Objective: The primary objective is to determine exposure in the population, and coverage of routine vaccinations in children and elderly. The secondary objective is to coverage estimates with external benchmarks
Study Design: The main study design is a retrospective dynamic cohort study
Population: The source population comprises of all subjects registered with one of the ADVANCE participating databases, which can link vaccination and population data and have provided their willingness to participate. The study population comprises all persons who are registered during the study period that starts January 1, 2000 and ends December 31, 2018.
Outcome Parameters: Vaccine exposure and vaccine coverage
Data Sources: Electronic health care databases (vaccine registries, record linkage, surveillance and GP based databases) currently available in the ADVANCE consortium and eligible are located in Denmark, Spain, Italy, UK and Netherlands
Informative data sources
Vaccine schedules: European Centre for Disease Prevention and Control (ECDC) vaccine schedules in Europe and national statistics on vaccination coverage
Benchmark data: WHO estimates for following vaccines/doses in a country: BCG, DTP1, DTP3, HepB_BD, HepB3, Hib3, IPV1, MCV1, MCV2, PCV3, Pol3, RCV1, Rota, http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveredtp literature for HPV (Bruni, Lancet Global Health) and influenza (VENICE)

Study status

Planned

Research institutions and networks

Institutions

P95 Clinical and Epidemiology Services

- ☐ Belgium
- ☐ Colombia
- ☐ Netherlands
- ☐ South Africa
- ☐ Thailand
- ☐ United States

First published: 07/11/2022

Last updated: 21/02/2025

Institution

Laboratory/Research/Testing facility

Non-Pharmaceutical company

ENCEPP partner

VACCINE.GRID

- ☐ Switzerland

First published: 26/06/2012

Last updated: 20/08/2024

Institution

Not-for-profit

Aarhus University & Aarhus University Hospital
DEPARTMENT OF CLINICAL EPIDEMIOLOGY

☐ Denmark

First published: 20/07/2021

Last updated: 02/04/2024

Institution

Educational Institution

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

Centre for Health Protection (RIVM-GZB), National Institute for Public Health & Environment

☐ Netherlands

First published: 06/11/2022

Last updated: 27/03/2024

Institution

EU Institution/Body/Agency

Laboratory/Research/Testing facility

ENCePP partner

P95 Clinical and Epidemiology Services

- ☐ Belgium
- ☐ Colombia
- ☐ Netherlands
- ☐ South Africa
- ☐ Thailand
- ☐ United States

First published: 07/11/2022

Last updated: 21/02/2025

Institution

Laboratory/Research/Testing facility

Non-Pharmaceutical company

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

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

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

Sciensano Brussels, RIVM the Netherlands, RCGP-RSC United Kingdom, PEDIANET Italy, ATS-Valpadana Italy, Pfizer USA

Networks

Accelerated development of vaccine benefit-risk collaboration in Europe (ADVANCE)

First published: 01/02/2024

Last updated: 01/02/2024

Network

Pedianet network (So.Se.Te)

☐ Italy

First published: 23/10/2025

Last updated: 23/10/2025

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Miriam Sturkenboom

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/10/2013

Actual: 01/10/2013

Study start date

Planned: 01/02/2019

Data analysis start date

Planned: 02/02/2019

Date of interim report, if expected

Planned: 31/03/2019

Date of final study report

Planned: 31/03/2019

Sources of funding

- EU institutional research programme

More details on funding

Innovative Medicines Initiative

Study protocol

[ADVANCEPOC_2protocolv1.020190201_clean.pdf](#) (744.23 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 type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

To assess exposure and coverage to routine vaccinations

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07B) VIRAL VACCINES

VIRAL VACCINES

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

35000000

Study design details

Outcomes

Counts and coverage, Comparisons against WHO benchmarks

Data analysis plan

Exposure and coverage estimation using point prevalence, point prevalence adjusted for follow-up and cumulative distribution function

Data management

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)

Danish registries (access/analysis)

The Information System for Research in Primary Care (SIDIAP)

BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

ARS Toscana

Pedianet

Data source(s), other

Danish Registries (access/analysis), SIDIAP, BIFAP, ARS, Pedianet

Data sources (types)

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

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

[Other](#)

Data sources (types), other

Exposure 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