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

Study description

Rationale and Background: To increase readiness of European data sources to conduct multi-site vaccine coverage, benefit and risk studiesResearch 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 benchmarksStudy Design: The main study design is a retrospective dynamic cohort studyPopulation: 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 NetherlandsInformative data sourcesVaccine schedules: European Centre for Disease Prevention and Control (ECDC) vaccine schedules in Europe and national statistics on vaccination coverageBenchmark 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/tswucoveragedtp literature for HPV (Bruni, Lancet Global Health) and influenza (VENICE)

Study status

Planned

Research institutions and networks

Institutions

P95 Julius Clinical (former P95 Clinical and Epidemiology Services)

Belgium
Colombia
Netherlands
South Africa
Thailand
United States

First published: 07/11/2022

Last updated: 24/09/2026

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 CLINICAL EPIDEMIOLOGY AND DATA SCIENCE, DEPARTMENT OF CLINICAL MEDICINE

Denmark

First published: 20/07/2021

Last updated: 20/10/2026

Institution | Educational Institution

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: 30/03/2026

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

P95 Julius Clinical (former P95 Clinical and Epidemiology Services)

Belgium
Colombia
Netherlands
South Africa
Thailand
United States

First published: 07/11/2022

Last updated: 24/09/2026

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: 09/07/2026

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: 08/04/2026

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

35.000.000

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

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)

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