# DARWIN EU® - Encephalitis risk in pediatric varicella vaccine recipients

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## Administrative details

EU PAS number	
EUPAS1000000813	
Study ID	
1000000813	
DARWIN EU® study	
Yes	
Study countries	
Denmark	
Finland	
Norway	
Spain	

Study status

Planned

Research institutions and networks

# Institutions

Department of Medical Informatics - Health Data
Science, Erasmus Medical Center (ErasmusMC)
☐ Netherlands
First published: 03/11/2022
<b>Last updated:</b> 02/05/2024
Institution

# **Networks**

Data Analysis and Real World Interrogation Network (DARWIN EU®)
☐ Belgium
☐ Croatia
☐ Denmark
Estonia
Finland
France
Germany
☐ Greece
Hungary
Italy
☐ Netherlands
Norway

Portugal
Spain
Sweden
United Kingdom
First published: 01/02/2024
<b>Last updated:</b> 30/04/2025

## Contact details

#### **Study institution contact**

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Study contact

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## **Primary lead investigator**

Xintong Li

**Primary lead investigator** 

# Study timelines

## Date when funding contract was signed

Planned: 14/07/2025

## Study start date

Planned: 28/11/2025

#### Date of final study report

Planned: 27/02/2026

# Sources of funding

EMA

## 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 type:

Non-interventional study

#### Main study objective:

1. To describe the vaccine uptake of V/MMRV by vaccine type, dose, brand, country, and to describe the characteristics of vaccine recipients.

- 2. To describe the background rates of encephalitis in the general paediatric population, and to estimate the crude incidence rates of encephalitis following varicella infection/chickenpox diagnosis.
- 3. To assess the association between V/MMRV vaccines and varicella infection (chickenpox) with encephalitis among children and adolescents aged 9 months to 18 years by age group and country

# 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The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## 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