

# DARWIN EU® Age specific incidence rates of RSV related disease in Europe

**First published:** 28/11/2023

**Last updated:** 27/06/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS107708

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### Study ID

107880

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### DARWIN EU® study

Yes

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### Study countries

 Estonia

 France

 Germany

 Spain

 United Kingdom

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## **Study description**

Rationale and Background: Severe acute respiratory infection caused by respiratory syncytial virus (RSV) poses a global health threat, especially impacting children under 5 and older adults, leading to significant morbidity and mortality. The ongoing development of RSV vaccines underscores the critical need for accurate information on RSV burden in high-risk groups, essential for continuous benefit/risk profile assessment. This study aims to provide crucial insights into age-specific incidence rates of RSV-related disease in Europe, contributing to ongoing efforts in comprehending and managing RSV infection burdens.

Research question: What are the age-specific disease frequencies, hospitalisation rates, and mortality rates of RSV infection in European countries over the past decade?

Study objectives: To estimate RSV-related hospitalization rates and duration, proportions of RSV-related ICU admissions and co-infection with other respiratory pathogens, as well as RSV-related mortality rates.

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## **Study status**

Finalised

## **Research institutions and networks**

### **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

**Last updated:** 30/04/2025

**Network**

## Contact details

### Study institution contact

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**Study contact**

[study@darwin-eu.org](mailto:study@darwin-eu.org)

## Primary lead investigator

Johnmary Arinze

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 15/09/2023

Actual: 15/09/2023

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### Study start date

Planned: 01/01/2013

Actual: 01/01/2013

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### Date of final study report

Planned: 31/12/2023

Actual: 27/02/2024

## Sources of funding

- EMA

## Study protocol

[DARWIN\\_EU\\_D2.2.3\\_Protocol\\_P2\\_C1-011\\_RSV\\_v2.1.pdf](#) (1.02 MB)

## 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 type:**

Non-interventional study

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#### **Study design:**

A cohort study will be conducted using routinely collected health data from 6 databases.

#### **Main study objective:**

To estimate the incidence of RSV related hospitalizations and the prevalence of RSV co infections with other respiratory pathogens specifically Influenza Viruses Rhinoviruses SARS CoV 2 Parainfluenza Viruses Adenoviruses Metapneumovirus and Enteroviruses in the general population stratified by year and age groups.

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Medical condition to be studied**

Respiratory syncytial virus infection

Respiratory syncytial virus bronchiolitis

Respiratory syncytial virus bronchitis

Influenza

H1N1 influenza

Pneumonia

Upper respiratory tract infection

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### **Additional medical condition(s)**

Acute bronchiolitis due to respiratory syncytial virus, Pneumonia due to respiratory syncytial virus, Acute respiratory syncytial virus bronchitis, Bronchopneumonia due to respiratory syncytial virus, Healthcare associated respiratory syncytial virus disease, Positive sputum culture for hRSV (Human respiratory syncytial virus), Respiratory syncytial virus laryngotracheobronchitis, Respiratory syncytial virus pharyngitis, Bronchiolitis caused by influenza virus

## Population studied

### **Age groups**

- 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)
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### **Estimated number of subjects**

22700000

## Study design details

### **Outcomes**

RSV related hospitalization ICU admission mortality rate and co infection with a range of other respiratory pathogens including Influenza Viruses Rhinoviruses SARS CoV 2 Parainfluenza Viruses Adenoviruses Metapneumovirus and Enteroviruses.

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### **Data analysis plan**

Analyses will be conducted separately for each database. Before study initiation test runs of the analytics are performed on a subset of the data sources or on a simulated set of patients and quality control checks are performed. Once all the tests are passed the final package is released in the version controlled Study Repository for execution against all the participating data sources. The data partners locally execute the analytics against the OMOP CDM in R Studio and review and approve the by default aggregated results before returning them to the Coordination Centre. Sometimes multiple execution iterations are performed and additional fine tuning of the code base is needed. A service desk will be available during the study execution for support. The study results of all data sources are checked after which they are made available to the team and

the Study Dissemination Phase can start. All results are locked and timestamped for reproducibility and transparency.

## Documents

### Study report

[DARWIN\\_EU\\_D2.2.4\\_Report\\_P2-C1-011\\_RSV\\_v2.2\\_Public.pdf](#) (1.45 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)

Institut Municipal d'Assistència Sanitària Information System / Hospital del Mar / PSMAR / (Hospital del Mar Information System)

Clinical Practice Research Datalink (CPRD) GOLD

IQVIA Disease Analyzer Germany

The Information System for Research in Primary Care (SIDIAP)

Estonian Biobank

Clinical Data Warehouse of the Bordeaux University Hospital

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### Data sources (types)

Electronic healthcare records (EHR)

Other

## Use of a Common Data Model (CDM)

### **CDM mapping**

Yes

### **CDM Mappings**

#### **CDM name**

OMOP

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#### **CDM website**

<https://www.ohdsi.org/Data-standardization/>

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## 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