

# Programme d'évaluation de la vaccination COVID-19 : Risque d'effets indésirables d'intérêt des différents vaccins et comparaison du bénéfice-risque des vaccins (EVACOV-RISC)

**First published:** 08/03/2023

**Last updated:** 23/07/2024

Study

Planned

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/104059>

### EU PAS number

EUPAS103839

### Study ID

104059

### DARWIN EU® study

No

## Study countries

☐ France

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## Study status

Planned

# Research institutions and networks

## Institutions

### University of Bordeaux

☐ France

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

**Educational Institution**

## Contact details

### Study institution contact

Nicolas Thurin

**Study contact**

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### Primary lead investigator

Nicolas Thurin

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Actual: 17/10/2022

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**Study start date**

Planned: 31/12/2022

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**Date of final study report**

Planned: 30/09/2026

## Sources of funding

- Other

## More details on funding

Ministère de l'Enseignement supérieur, de la Recherche et de l'Innovation via  
l'ANRS-Maladies Infectieuses Emergentes

## Regulatory

**Was the study required by a regulatory body?**

No

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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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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

**Main study objective:**

The first objective is to evaluate the incidence rate of each adverse event of special interest (AESI) following the introduction of various anti-COVID-19 vaccines in the French population compared to the baseline rates estimated just before their introduction. The second one is to compare the risk of each AESI between vaccinated and non-vaccinated persons, and between the different vaccines.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(J07BX) Other viral vaccines

Other viral vaccines

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## **Medical condition to be studied**

COVID-19 immunisation

## Population studied

### **Age groups**

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**

6700000

## Study design details

### **Outcomes**

The primary outcomes are the AESIs included in the list set up in collaboration with the EMA.

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### **Data analysis plan**

For each year (2021, 2022, 2023) in the SNDS, 3 cohorts will be defined: one on a random sample of 10% of the French population, one on all patients with an AESI, and one on all pregnant women. For the first objective, the incidence rate of each AESI will be compared before (2017-2020) and after the introduction of vaccines. Interrupted time series and time-to-onset analyses related to the date of vaccination should complete these elements. For the second objective, a

comparative approach relying on propensity score matching will be set up to assess AESI relative risks between vaccinated and non-vaccinated subjects. A self-controlled risk interval design will also be implemented for all suitable AESIs.

## Data management

### Data sources

**Data source(s), other**

SNIRAMSNDs France

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**Data sources (types)**

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

### Use of a Common Data Model (CDM)

**CDM mapping**

No

### 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