

# A Phase 4 Observational, Real-World Study of 20-valent Pneumococcal Conjugate Vaccine Effectiveness Against Vaccine-Type Invasive Pneumococcal Disease in Adults Aged 65 years and above

**First published:** 27/03/2024

**Last updated:** 04/07/2025

Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000007

### Study ID

1000000007

### DARWIN EU® study

No

### Study countries

- Czechia
- Israel

Spain

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## 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

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**Institution**

**Laboratory/Research/Testing facility**

**Non-Pharmaceutical company**

**ENCePP partner**

## Contact details

### Study institution contact

Germaine Hanquet germaine.hanquet@p-95.com

## Study contact

[germaine.hanquet@p-95.com](mailto:germaine.hanquet@p-95.com)

### Primary lead investigator

Germaine Hanquet 0000-0002-3382-0211

#### Primary lead investigator

### ORCID number:

0000-0002-3382-0211

## Study timelines

### Date when funding contract was signed

Planned: 01/06/2024

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### Study start date

Planned: 01/09/2024

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### Date of final study report

Planned: 31/12/2028

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## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

## Regulatory

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

Yes

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### **Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 2 (specific obligation of marketing authorisation)

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### **Regulatory procedure number**

EMEA/H/C/005451

## Methodological aspects

### Study type

#### Study type list

##### **Study topic:**

Human medicinal product

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##### **Study type:**

Non-interventional study

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##### **Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

No individual level data collected for the purpose of the study

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**Study design:**

A multi-country observational study using the indirect cohort (Broome) method will be conducted, in which cases are IPD caused by vaccine serotypes and controls are IPD caused by non-20vPnC serotypes.

**Main study objective:**

To estimate vaccine effectiveness of 20vPnC against IPD due to any of the 20 serotypes that are included in the vaccine (20vPnC serotypes), in adults aged 65 years and above.

## Study Design

**Non-interventional study design**

Case-control

## Study drug and medical condition

**Medicinal product name**

PREVENAR 20

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**Medicinal product name, other**

Prevenar 20

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**Anatomical Therapeutic Chemical (ATC) code**

(J07AL) Pneumococcal vaccines

Pneumococcal vaccines

(J07AL02) pneumococcus, purified polysaccharides antigen conjugated pneumococcus, purified polysaccharides antigen conjugated

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

Severe invasive streptococcal infection

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

Invasive pneumococcal disease (IPD)

## Population studied

### **Short description of the study population**

Adults aged 65 years and above with IPD with an identified pneumococcal serotype who were reported to the study site surveillance system and were eligible for 20vPnC vaccination, according to local vaccination policies.

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### **Age groups**

- Elderly ( $\geq$  65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)

## Study design details

### **Setting**

Study sites are national or regional surveillance systems, or hospital research networks, selected based on existing 20vPnC recommendation in adults,

expected vaccine uptake, expected number of serotyped IPD cases, and availability of data on vaccination status. IPD data for all adults aged 18 years and above will be collected to monitor serotyping distribution. Participating sites will contribute up to four years of data.

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## **Comparators**

NA

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## **Outcomes**

Primary outcome will be IPD due to any of the 20vPnC serotypes; Secondary outcomes: IPD due to any of the 13vPnC serotypes; and IPD due to any of the 7 20non13vPnC serotypes

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## **Data analysis plan**

Study sites will submit a de-identified dataset to the study sponsor (P95). Descriptive statistics for every site and pooled for all sites will be performed. For every objective, unadjusted and adjusted VE against vaccine serotype IPD will be estimated as  $VE = (1 - \text{odds ratio (OR)}) \times 100\%$ , where OR denotes the odds ratio, comparing the odds of vaccination among vaccine serotype IPD (cases) to the odds of vaccination among non-vaccine serotype IPD (controls). VE estimates will be adjusted for the major confounding factors (i.e., study site, year of IPD diagnosis, age). Previous pneumococcal vaccination will be considered in the analysis. VE pooled estimates will be stratified by age group and time since 20vPnC vaccination (e.g., <2 years, 2-5 years after vaccination).

## **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), other**

Data sources per IPD patient, including serotyping, patient-level information and exposure ascertainment will differ across study sites and may include national/regional IPD surveillance system, patient medical records, and vaccination registries. Study sites will submit a de-identified dataset to the study sponsor.

## 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