

# Real-world characteristics, management and outcomes of subjects screened or diagnosed with COVID-19 in Spain (COVID-19 REAL)

**First published:** 31/03/2020

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS34411

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### Study ID

46384

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### DARWIN EU® study

No

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### Study countries

 Spain

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### Study description

The study is a non-interventional, retrospective, database, cohort study based on anonymized and routinely-collected health care data from several Spanish Hospitals which have been mapped to the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM). The present study aims to participate in the OHDSI international collaboration by analyzing data from Spain. Further analyses to answer specific, local COVID-19 research questions that may arise during the ongoing crisis might be also considered.

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### TFS HealthScience (TFS)

 Sweden

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

**Last updated:** 03/04/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

#### University Hospital Vall d'Hebron (HUVH)

 Spain

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

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

Institution

Educational Institution

Hospital/Clinic/Other health care facility

## Parc de Salut Mar Barcelona (PSMAR)

 Spain

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

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

Institution

Hospital/Clinic/Other health care facility

Hospital Vall Hebron Barcelona (Spain), Hospital del Mar Barcelona (Spain), Hospital de Cruces Barakaldo (Spain), Hospital San Eloy Barakaldo (Spain), Hospital Urduliz Urduliz (Spain)

## Contact details

### Study institution contact

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Study contact

[neus.valveny@tfscro.com](mailto:neus.valveny@tfscro.com)

### Primary lead investigator

Neus Valveny

## Study timelines

### **Date when funding contract was signed**

Planned: 31/03/2020

Actual: 14/05/2020

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### **Study start date**

Planned: 09/12/2020

Actual: 09/12/2020

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### **Data analysis start date**

Planned: 15/12/2020

Actual: 15/12/2020

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### **Date of interim report, if expected**

Planned: 01/03/2020

Actual: 01/03/2021

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### **Date of final study report**

Planned: 31/12/2021

Actual: 01/03/2022

## Sources of funding

- Other

## More details on funding

TFS, IOMED, Bill Gates Foundation (through Oxford University)

## Study protocol

[OHDSI COVID-19 Real\\_protocol\\_25Mar20.pdf](#) (649.19 KB)

## 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

## Other study registration identification numbers and links

YOC-CLO-2020-01 (AEMPS identification number)

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Main study objective:**

Describing the characteristics of subjects screened and/or diagnosed with COVID-19 in Spain  
Describing therapeutic management in the clinical practice  
Describing clinical outcomes for the infected subjects  
Assessing predictor factors for infection, hospitalization, intensive care admission and death  
Exploring effectiveness and safety of administered therapies

## Study Design

**Non-interventional study design**

Case-control

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Pneumonia

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**Additional medical condition(s)**

COVID-19  
Pneumonia  
Viral Infection

## Population studied

**Age groups**

- Adolescents (12 to < 18 years)
  - Children (2 to < 12 years)
  - Infants and toddlers (28 days - 23 months)
  - Term newborn infants (0 - 27 days)
  - 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**

8000

## Study design details

### **Outcomes**

Sociodemographic and lifestyle Geographical/Ethnic origin History of exposure to COVID-19 and dates, test results and viral load, if available Current and past concomitant medications Current and past comorbidities Diagnosis, clinical symptoms and signs Laboratory values Severity scores, Infection status Pneumonia status Recovery status and time to recovery Hospitalization and length of stay ICU admission and length of stay Overall survival Complications during infection (bacterial pneumonia, sepsis...) Recurrence/reinfection

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### **Data analysis plan**

Descriptive analysis in the overall sample and by subgroups of interest (e.g. Hospital, gender, age subgroups, smoking history, diabetes status, cardiovascular history etc.) Multivariable Cox Regression to estimate Hazard ratios Multivariable Logistic Regression to estimate Odds ratios

## Documents

## Study publications

[Reyes C, Pistillo A, Fernández-Bertolín S, Recalde M, Roel E, Puente D, Sena AG...](#)

[Kostka K, Duarte-Salles T, Prats-Uribe A, Sena AG, Pistillo A, Khalid S, Lai LY...](#)

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## 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 sources (types)

[Electronic healthcare records \(EHR\)](#)

[Other](#)

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### Data sources (types), other

Routine Hospital Electronic Medical Records

## 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