# Registry to study factors that may impact COVID-19 occurrence and severity (CARE)

**First published:** 13/07/2020

**Last updated:** 14/03/2024

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS36240

**Study ID**

45755

**DARWIN EU® study**

No

**Study countries**

United Kingdom

United States

**Study description**

This is an observational, direct-to-participant, web-based, longitudinal study of adults with potential exposure to COVID-19 to better understand risk factors,

symptoms, and treatments for COVID-19 illness.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### IQVIA

United Kingdom

**First published:** 12/11/2021

**Last updated:** 22/04/2024

**Institution** **Non-Pharmaceutical company** **ENCePP partner**

# Contact details

**Study institution contact**

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**Study contact**

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**Primary lead investigator**

Dreyer Nancy

**Primary lead investigator**

# Study timelines

**Date when funding contract was signed**
Planned: 01/04/2020

Actual: 01/04/2020

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**Study start date**
Planned: 22/04/2020

Actual: 22/04/2020

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**Data analysis start date**
Planned: 28/04/2020

Actual: 28/04/2020

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**Date of final study report**
Planned: 14/01/2022

# Sources of funding

- Pharmaceutical company and other private sector
- Other

# More details on funding

Pfizer, FDA, IQVIA

# Regulatory

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

No

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

Not applicable

## Other study registration identification numbers and links

Participants enter information here:,https://www.helpstopcovid19.com/

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

**Main study objective:**

The objective of this study is to identify factors that may impact the occurrence or severity of COVID-19 infections including examining the role of underlying health conditions, prescription and over-the-counter medications, vitamins and supplements. In the US, comparative COVID vaccine safety and effectiveness is

also under study.

## Study Design

**Non-interventional study design**

Cohort

Case-control

## Study drug and medical condition

**Medical condition to be studied**

COVID-19

## Population studied

**Age groups**

- 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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**Special population of interest**

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

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**Estimated number of subjects**

35000

## Study design details

**Outcomes**

Testing positive for COVID-19 and symptom severity, Vaccination for COVID-19

**Data analysis plan**

Analyses depend on the research question. Analytic plans are developed at the outset of every research question, as they are identified. For vaccine effectiveness, we are using the test-negative control design

## Documents

**Study publications**

Dreyer NA, Reynolds M, Mack CD, Brinkley E, Petruski-Ivelva N, Hawaldar K, Toov…

Dreyer NA, Reynolds MW, Albert LM, Brinkley E, Kwon T, Mack CD, Toovey S. How f…

Reynolds MW, Secora A, Joules A, Albert L, Brinkley E, Kwon T, Mack CD, Toovey …

Dreyer N, Petruski-Ivleva N, Albert L, Mohamed D, Brinkley E, Reynolds M, Toove…

Dreyer NA, Reynolds MW. Using Community Reporters as a Strategic Source for Eva…

# 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)**

Other

**Data sources (types), other**

Prospective patient-based data collection

## 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