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

Study start date
Planned: 22/04/2020

Actual: 22/04/2020

Data analysis start date
Planned: 28/04/2020

Actual: 28/04/2020

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)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

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