A standing cohort to understand the characteristics of patients with COVID-19 and contextualize the COVID-19 complication and safety events of interests using US OPTUM EHR data

First published: 15/11/2022

Last updated: 19/03/2026

Study Finalised

Administrative details

EU PAS number

EUPAS48654

Study ID

48655

DARWIN EU® study

No

Study countries

United States

Study description

The main purpose of the study is to understand the characteristics and healthcare utilization of patients with COVID 19 and to examine the COVID 19 complication and safety events of interests.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

scott.kelly@pfizer.com

Primary lead investigator

Scott Kelly

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 07/09/2022

Actual: 07/09/2022

Study start date
Planned: 01/05/2022

Actual: 01/05/2022

Date of final study report
Planned: 27/02/2026

Actual: 18/02/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

C4671040 NIS Protocol V1_Final 29Apr2022_Redacted.pdf (8.55 MB)

C4671040 Non Interventional Study Protocol Amendment 2_Version 3.0_(clean)_23Aug2022_Redacted.pdf (4.74 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Feasibility analysis

Data collection methods:

Secondary use of data

Main study objective:

This study aims to understand the characteristics of patients with COVID-19 and contextualize the COVID-19 complication and safety events of interests using

real world data.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

PAXLOVID

Study drug International non-proprietary name (INN) or common name

NIRMATRELVIR

RITONAVIR

Anatomical Therapeutic Chemical (ATC) code

(J05AE30) nirmatrelvir and ritonavir

nirmatrelvir and ritonavir

Medical condition to be studied

SARS-CoV-2 test positive

COVID-19

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)

Study design details

Outcomes

Distribution of demographics, medical history, biomarkers, health-equity, healthcare utilization and time to clinical events at baseline for COVID-19 patients. Background incidence of COVID-19 manifestations and safety outcomes for COVID-19 patients. Incidence of long COVID-19, Incidence of oxygen supplementation among COVID-19 patients hospitalized with mechanical ventilation/ECMO Predictors of COVID-19 severe outcomes/manifestations and long COVID Real world effectiveness of Paxlovid in reducing the COVID-19 related outcomes.

Data analysis plan

Baseline characteristics will be summarized for COVID 19 patients in the study. Means with standard deviations, medians with interquartile will be provided for continuous variables. Numbers and percentages will be provided for dichotomous variables or categorical variables. For dichotomous endpoints such as COVID-19 complications and outcomes, the crude cumulative incidence and incidence rate of each endpoint will be estimated. To assess the feasibility of real-world effectiveness of Paxlovid, we will apply propensity score matching (PSM) method to control confounding and prescription time distribution method (PTDM) to handle immortal bias. For exploratory analysis, machine learning

models (eg, LASSO Cox regression, Random Survival Forest (RSF), and XGBoosting (XGB) models) will be used to identify important predictors associated with progression to COVID-19 severe outcomes/manifestations as well as long COVID.

Documents

Abstract of study report

C4671040 Non-Interventional-Low-Interventional Study Type 1 Study Report Abstract_18Feb2026_Redacted.pdf (123.62 KB)

Study report

C4671040 Non-Interventional-Low-Interventional Study Type 1 Study Report_Final_18Feb2026_Redacted.pdf (3.84 MB)

Study, other information

C4671040 Non Interventional Protocol V2 Amendment 1 Study Abstract 19 August 22_Redacted.pdf (1.93 MB)

C4671040 Non Interventional Protocol V3 Amendment 2 Study Abstract 23 August 22_Redacted.pdf (1.93 MB)

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)

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