# Viral SARS-CoV-2 rebounds in commercial pharmacy-based SARS-CoV-2 PCR testing

**First published:** 23/02/2023

**Last updated:** 12/09/2024

Study Finalised

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/105624

**EU PAS number**

EUPAS103517

**Study ID**

105624

**DARWIN EU® study**

No

**Study countries**

☐ United States

**Study description**

This is a non-interventional, retrospective cohort study using secondary data sources containing structured data from the US. This study will include adults (≥18 years of age) and pediatric participants (<18 years of age) with a positive SARS-CoV-2 test (e.g. positive polymerase chain reaction (PCR) of direct SARS-CoV-2 viral testing). This study will be conducted using SARS-CoV-2 diagnostic testing data from the Helix Respiratory Registry with linkage to the retrospective Komodo Healthcare claims data during the period of June 01, 2020, to February 28, 2023. Viral SARS-CoV-2 rebound will be examined after stratification of variables such as SARS-CoV-2 therapeutic treatment, viral load patterns, high-risk status for progression to severe SARS-CoV-2, age (<50 years of age versus 50+ years of age), and by timing around rebounds in relation to initial test positivity to treatment for SARS-CoV-2.

---

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Pfizer

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

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

**Institution**

### Helix OpCo, LLC

# Contact details

**Study institution contact**

Scott Kelly

Study contact

Scott.Kelly@pfizer.com

**Primary lead investigator**

Scott Kelly

Primary lead investigator

# Study timelines

**Date when funding contract was signed**

Planned: 17/11/2022

Actual: 17/11/2022

---

**Study start date**

Planned: 22/02/2023

Actual: 23/02/2023

---

**Data analysis start date**

Planned: 14/07/2023

Actual: 14/07/2023

---

**Date of final study report**

Planned: 14/08/2024

Actual: 13/08/2024

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

C4671048 NI APPROVED PROTOCOL_FINAL_V1.0_08FEB2023_redacted.pdf
(463.38 KB)

## 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 type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

**Main study objective:**

To estimate viral SARS-CoV-2 rebound rates, prior to the Omicron era and during the Omicron era, in high frequency (volume) SARS-CoV-2 diagnostic testers overall, and among those treated with Paxlovid/nirmatrelvir-ritonavir for SARS-CoV-2 versus those with no evidence of SARS-CoV-2 treatment (untreated for SARS-CoV-2).

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine**

PAXLOVID

---

**Medical condition to be studied**

COVID-19

## Population studied

**Age groups**

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)

---

**Estimated number of subjects**

21911

## Study design details

**Outcomes**

SARS-CoV-2 rebound where the main definition of rebound is 1) a positive test (at the index date), followed by a single negative test, followed by a positive test within 28 days or 2) 1 or more positive tests starting at the index date, followed by 1 or more negative tests, followed by a positive test within same 28-day time span.

---

**Data analysis plan**

Descriptive statistics among individuals with SARS-CoV-2 in the Helix Respiratory Registry that overlap with the retrospective Komodo Healthcare claims data will be summarized. Means with standard deviations, medians with interquartile ranges will be provided for continuous variables. Numbers and percentages will be provided for dichotomous variables or categorical variables. For exploratory analyses, logistic regression or Cox proportional hazards regression models will be used to identify risk factors and outcomes for SARS-CoV-2 rebound in adjusted analyses. Model selection will balance biological and contextual knowledge for potential confounders with statistical considerations for model fit and the bias versus variance tradeoff. Detailed methodology for summary and statistical analyses of data collected in this study will be

documented in a statistical analysis plan (SAP), which will be dated, filed, and maintained by the sponsor.

## Documents

**Study report**

C4671048 Non Interventional Final Study Report_13Aug2024_R.pdf(2.23 MB)

**Study, other information**

C4671048 Non Interventional Study Report Abstract_13Aug2024_R.pdf(89.57 KB)

# Data management

## Data sources

**Data source(s), other**

Helix Respiratory Registry United States, Komodo Healthcare claims data United States

---

**Data sources (types)**

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Yes

**Check completeness**

Yes

**Check stability**

Unknown

**Check logical consistency**

Yes

## Data characterisation

**Data characterisation conducted**

Unknown