COVID-19 and Real-World Evidence: A Scoping Review on Factors That Affected Real-World Data Quality and Collection during the Pandemic and Methods to Address these Issues

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Study Planned

Administrative details

EU PAS number

EUPAS1000000057

Study ID

1000000057

DARWIN EU® study

No

Study countries

☐ Netherlands

Study description

The COVID-19 pandemic has been linked to a unique situation with several periods of lock down, at least in some EU countries, and some changes in the way patients got access to the healthcare system. This is particularly true for the years 2020 and 2021.

In pharmacoepidemiology, we often use real world data to generate real world evidence, data which have been collected in data sources under routine clinical care. Any change in this routine setting has an impact on the way data are collected and reported and then possibly used for non-interventional studies to support regulatory decision making. Nowadays, data from this period (2020-2021) available in these data sources may represent a different pattern of reporting collection than the years before and the years after the pandemic period. How to handle data collected during the pandemic is a real question as well as understanding of the potential issues linked to the data collection that occurred during the pandemic situation in many European countries and its impacts in the current use of such data for regulatory purposes.

Study status

Planned

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

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Study timelines

Date when funding contract was signed

Planned: 04/10/2023

Study start date

Planned: 10/03/2024

Date of final study report

Planned: 04/10/2024

Study protocol

Study Protocol 10032024.pdf(156.53 KB)

Study Protocol 19042024.pdf(157.37 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Not applicable

Data management

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

No

Check stability

No

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No