Bayesian Evaluation of Time-To-Event and Reliability (for vaccine surveillance) (BETTER)

First published: 17/08/2022

Last updated: 17/08/2022

Study Ongoing

Administrative details

EU PAS number

EUPAS48616

Study ID

48617

DARWIN EU® study

No

Study countries

☐ United States

Study description

As various approved COVID-19 vaccines are rolled out globally, safety signals have been identified from spontaneous reports and other data sources. The current standard method of safety surveillance adopted by the FDA is MaxSPRT, which suffers from the inflexibility of a pre-specified sequential analysis schedule. We hope to develop and implement a more flexible Bayesian surveillance framework and compare its performance with MaxSPRT in real-world data. To compare the real-data performance (testing errors, timeliness, precision and bias) of Bayesian and frequentist sequential analysis methods for the study of comparative vaccine safety. We will also produce a reference table of Type I and II error rates and signal detection times for all combinations of design and threshold choices, as exploration of the operating characteristics of Bayesian sequential methods.

Study status

Ongoing

Research institutions and networks

Institutions

Observational Health Data Sciences and Informatics (OHDSI)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Networks

Observational Health Data Sciences and Informatics (OHDSI) Network

First published: 01/02/2024

Last updated: 01/02/2024

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Marc Suchard

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 28/08/2021

Study start date

Actual: 01/01/2022

Data analysis start date
Actual: 01/02/2022

Date of final study report
Planned: 30/09/2022

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Johnson & Johnson, US Food & Drug Administration, US Department of Veterans Affairs, US National Institutes of Health

Study protocol

BETTER_protocol.pdf (214.13 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:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Methods research

Main study objective:

To compare the real-data performance (testing errors, timeliness, precision and bias) of Bayesian and frequentist sequential analysis methods for the study of comparative vaccine safety.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Self-controlled case series, Historical rate comparison

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07B) VIRAL VACCINES

VIRAL VACCINES

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)

Estimated number of subjects

2000000

Study design details

Data analysis plan

Exposures: previous viral vaccines including 2017-2018 flu, H1N1 flu, Human Papillomavirus (HPV), and Varicella-Zoster. Outcomes: selected adverse events of special interest, negative control outcomes, imputed positive control outcomes. Analysis design: self-controlled case series & historical comparator.

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 source(s), other

IBM MarketScan Commercial Claims and Encounters (CCAE) United States, IBM MarketScan Medicare Supplemental Database (MDCR) United States, IBM MarketScan Multi-State Medicaid Database (MDCD) United States, Optum Clinformatics Data Mart (Optum) United States, Optum Electronic Health Records (OptumEHR) United States

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Data sources (types)

Administrative healthcare records (e.g., claims)

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