# 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

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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

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**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

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**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)

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**Estimated number of subjects**

2.000.000

## 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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

## Data characterisation conducted

No