Observational influenza vaccine active surveillance study: A Phase IV Prospective Multi-Centre Cohort Study to Evaluate the Reactogenicity of bioCSL's influenza virus vaccine (2015/2016 formulation) (CSLCT-SAF-15-07)

First published: 28/08/2015

Last updated: 25/06/2025

Study Finalised

Administrative details

EU PAS number

EUPAS10613

Study ID

14346

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This protocol defines an enhanced active surveillance system that will collect and descriptively summarise participant self-reported reactogenicity data, which will be supplemented by primary care or other health provider data on the details of vaccination, and any Medically attended Adverse Events (MAE) in the seven day period after each bioCSL influenza vaccination in a given year.Descriptive summaries of the reactogenicity and other safety data as defined in the primary and secondary study objectives will allow indirect comparison of data from the study with previous safety data, and data arising from the enhanced safety surveillance system over time, to facilitate safety signal detection for bioCSL’s influenza virus vaccine.Primary objective is to characterise the reactogenicity (local, systemic and allergic reactions) within seven days after each influenza vaccination with bioCSL’s influenza virus vaccine in participants routinely indicated for influenza vaccination in specified age groups.Secondary objective is to assess the frequency and severity of medically attended adverse events occurring within seven days after each influenza vaccination with bioCSL’s influenza virus vaccine, in participants routinely indicated for influenza vaccination in specified age groups.

Study status

Finalised

Research institutions and networks

Institutions

Harbinson House Surgery

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Albany House Medical Centre

Knowle House surgery

Honiton Surgey

The Rame Group Practice United Kindgom

Bradford on Avon and Melksham Health Partnership

The Haven Surgery

University of Nottingham Health service

Axbridge & Wedmore Medical Practice

Westbury Group Practice

Pickering Medical Practice

Bradford Road Medical Centre

Networks

NIHR Medicines for Children Research Network

First published: 01/02/2024

Last updated: 01/02/2024

Network

Contact details

Study institution contact

Bibby David david.bibby@seqirus.com

Study contact

david.bibby@seqirus.com

Primary lead investigator

James Larcombe

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/06/2015

Actual: 24/06/2015

Study start date

Planned: 14/09/2015

Actual: 15/09/2015

Data analysis start date
Planned: 05/10/2015

Actual: 05/10/2015

Date of interim report, if expected
Planned: 15/10/2015

Actual: 15/10/2015

Date of final study report
Planned: 01/02/2016

Actual: 03/02/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

bioCSL Pty Ltd

Study protocol

CSLCT-SAF-15-07_PASS protocol_abstract v1.0.pdf (66.31 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 2 (specific obligation of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To characterise the reactogenicity (local, systemic and allergic reactions) within seven days after each influenza vaccination with bioCSL’s influenza virus vaccine in participants routinely indicated for influenza vaccination in specified age groups.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

TRIVALENT INFLUENZA VACCINE

Population studied

Short description of the study population

This observational post-marketing study is designed to capture the population receiving bioCSL’s influenza virus vaccine regardless of age or health status in order to provide a picture of the safety profile in routine practice. Pregnant and immune-compromised participants, and children aged less than 5 are not excluded from this study if they have been administered bioCSL’s influenza virus vaccine as part of routine care, or inadvertently prior to enrolment in the study. The source of the population will be people who present to general practice or pharmacies for influenza vaccination, either through mass vaccination clinics or opportunistic vaccination during routine consultations or pharmacy visit for the influenza vaccination season, and have received bioCSL’s influenza virus vaccine. Inclusion criteria:Receipt of at least one vaccination of bioCSL’s influenza virus vaccine after 1 July 2015

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)

Special population of interest

Immunocompromised

Pregnant women

Estimated number of subjects

400

Study design details

Outcomes

The reactogenicity of bioCSL’s influenza vaccine will be assessed by summarising reports of solicited adverse events occurring within seven days after each vaccination. Solicited events include injection site, systemic and allergic reactions. Participants will also be asked to indicate if they did not experience any adverse events to distinguish between no reported AE and missing data. Information on Medically attended Adverse Events (MAEs) will be recorded for medical attendances that relate to events occurring within seven days after each influenza vaccination.

Data analysis plan

Summary descriptive statistics of continuous data will be presented as number of observations, mean, standard deviation (SD), median, minimum and maximum. For categorical variables, statistical summaries will include counts and percentages relative to the appropriate population. Two sided 95% confidence intervals will be provided for descriptive statistics, as warranted.

Documents

Study results

RESULT SUMMARY for PASS 2015 - CSLCT-SAF-15-07_FINAL.pdf (85.64 KB)

Study, other information

LIST OF CENTRES WHERE THE STUDY IS BEING CONDUCTED.pdf (46.85 KB)

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.

Signed checklist for study protocols

CSLCT-SAF-15-07_PASS protocol_abstract v1.0_Annex2 (checklist).pdf (75.6 KB)

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Data collection will utilise a mix of investigator site data entry and participant (or parent/guardian) self-reported data entry into a web-accessed electronic database meeting appropriate observational research, regulatory and data protection standards.

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