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)

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### Administrative details

#### **EU PAS number**

**EUPAS10613** 

Study ID

14346

**DARWIN EU® study** 

No

**Study countries** 

### 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

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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

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### Contact details

### Study institution contact

Bibby David david.bibby@seqirus.com

Study contact

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### **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)?

# 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)</li>
- Adults (18 to < 46 years)</li>

- Adults (46 to < 65 years)</li>
- Adults (65 to < 75 years)</li>
- 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