# A/H1N1 pandemic vaccines and pregnancy outcomes

First published: 17/11/2010

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# Administrative details

EU PAS number	
EUPAS1705	
Study ID	
5304	
DARWIN EU® study	
Study countries  Denmark	
Finland Germany	
Italy  Netherlands  Sweden	

☐ United	Kingdom
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#### Study description

1) identification of relevant research centres, organisations and agencies active in the evaluation and safety of A/H1N1 vaccine safety in pregnant women,2) organise and coordinate an exchange of information between these centres, organisations and agencies with the aim to conduct a meta analysis of study results where appropriate,3) In collaboration with all stakeholders, produce a proposal for a long-term collaboration between research centres active in the field of drugs and pregnancy outcomes, including interaction with ENCePP, this deliverable will involve extending the profile of centres included in the inventory mentioned under 1)

#### **Study status**

Finalised

### Research institutions and networks

### **Institutions**

### University of Bath

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Institution

Electronic Health Records (EHR) Research Group, London School of Hygiene & Tropical Medicine

(LSHTM)
United Kingdom
First published: 19/04/2010
<b>Last updated:</b> 30/10/2024
Institution Educational Institution ENCePP partner



## Contact details

### **Study institution contact**

Corinne de Vries c.de-vries@bath.ac.uk

Study contact

c.de-vries@bath.ac.uk

### Primary lead investigator

Corinne de Vries

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Planned: 19/10/2010 Actual: 19/10/2010

#### Study start date

Planned: 19/10/2010 Actual: 26/10/2010

#### Data analysis start date

Planned: 30/11/2012

### Date of interim report, if expected

Planned: 19/07/2011

#### Date of final study report

Planned: 30/06/2013 Actual: 31/01/2013

# Sources of funding

EMA

# Regulatory

Was the study required by a regulatory body?

Yes

# Methodological aspects

# Study type

#### **Study topic:**

Human medicinal product

Disease /health condition

#### Study type:

Non-interventional study

#### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness Other

#### If 'other', further details on the scope of the study

Setting up a network for drug safety in pregnancy evaluation

#### **Data collection methods:**

Secondary use of data

#### Main study objective:

to identify all studies of H1N1 vaccine safety in pregnancy, to conduct meta analyses of the studies identified as appropriate, and to set up a network for evaluation of drug safety in pregnancy.

# Study Design

#### Non-interventional study design

Systematic review and meta-analysis

# Study drug and medical condition

#### Medicinal product name, other

INFLUENZA VIRUS, TYPE A, H1N1 7.0 LOG 10 FFU (FLUORESCENT FOCUS UNITS)
PER DOSE

#### Medical condition to be studied

Exposure during pregnancy

# Population studied

#### Short description of the study population

Pregnant women

#### Age groups

- Preterm newborn infants (0 27 days)
- Term newborn infants (0 27 days)
- Infants and toddlers (28 days 23 months)

#### Special population of interest

Pregnant women

#### **Estimated number of subjects**

2

# Study design details

#### **Outcomes**

1) inventory of studies, 2) quantification of adverse pregnancy outcomes, 3) establishment of network

#### Data analysis plan

We will establish whether it is appropriate to pool the data and to analyse the pooled data where appropriate. Heterogeneity in study results between participating centres will be identified, evaluated, and where necessary we will go back to the data suppliers for any additional verification exercises required. When appropriate, a pooled analysis will be carried out.

### **Documents**

#### **Study results**

EMA H1N1 Jan 2013\_EMA.pdf (186.87 KB)

#### **Study report**

Charlton\_DeVries\_Final report data sources for medicines in pregnancy research.pdf (312.26 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.

### Data sources

Data source(s)

#### Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

Drug registry

Other

#### Data sources (types), other

Prospective patient-based data collection, Case-control surveillance database

### 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