# A/H1N1 pandemic vaccines and pregnancy outcomes

**First published:** 17/11/2010

**Last updated:** 23/04/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS1705

**Study ID**

5304

**DARWIN EU® study**

No

**Study countries**

- Denmark
- Finland
- Germany
- Italy
- Netherlands
- Sweden

United Kingdom

**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

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

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

## (LSHTM)

United Kingdom

**First published:** 19/04/2010

**Last updated:** 04/11/2026

Institution | Educational Institution | ENCePP partner

## Pharmacy & Pharmacology, University of Bath

United Kingdom

**First published:** 30/04/2010

**Last updated:** 08/04/2019

Institution | Outdated | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

# Contact details

**Study institution contact**

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Study contact

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**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

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**Study start date**
Planned: 19/10/2010

Actual: 26/10/2010

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**Data analysis start date**
Planned: 30/11/2012

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**Date of interim report, if expected**
Planned: 19/07/2011

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**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

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**Study type:**

Non-interventional study

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**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

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**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)

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**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)**

Clinical Practice Research Datalink

**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