# Avian/Pandemic Influenza Registry (AVEX Registry)

**First published:** 12/08/2011

**Last updated:** 31/07/2012

Study Finalised

## Administrative details

**EU PAS number**

EUPAS2113

**Study ID**

2865

**DARWIN EU® study**

No

**Study countries**

- [ ] Azerbaijan
- [ ] Bangladesh
- [ ] Cambodia
- [ ] China
- [ ] Egypt
- [ ] Hong Kong

- [ ] Indonesia
- [ ] Lao People's Democratic Republic
- [ ] Nigeria
- [ ] Pakistan
- [ ] Thailand
- [ ] Türkiye
- [ ] Viet Nam

**Study description**

This is an observational patient registry of humans infected with avian influenza A (H5N1). The registry is a collaborative study involving members of the international scientific, medical and public health communities. The registry collects information from many countries on patients' exposures, symptoms, presentation for medical care, virologic testing, treatment, clinical course and survival in order to better understand the clinical course and effectiveness of current treatments for H5N1 infections in humans.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Scientific Affairs, Outcome SARL

- [ ] Switzerland

**First published:** 12/04/2010

**Last updated:** 20/08/2024

Institution | Other

Multiple centres: 9 centres involved in this study across 9 countries, list available on request

## Networks

Full list available on request

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Nancy Dreyer

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 01/01/2007

Actual: 12/12/2006

**Study start date**
Planned: 03/04/2007

Actual: 26/03/2007

**Data analysis start date**
Planned: 16/10/2007

Actual: 16/10/2007

**Date of interim report, if expected**
Planned: 15/07/2011

Actual: 18/07/2011

**Date of final study report**
Planned: 30/06/2012

Actual: 20/06/2012

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

F. Hoffmann-La Roche Ltd

## Study protocol

Avian-Pandemic Influenza Registry_Revised Protocol_16Oct08Final.pdf(119.72 KB)

## Regulatory

**Was the study required by a regulatory body?**

No

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Other

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**Study topic, other:**

Disease/Epidemiology study

**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To better understand the clinical course of infection with H5N1, and the effectiveness of curently treatments used in humans

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Case-series

## Study drug and medical condition

**Medical condition to be studied**

Avian influenza

## Population studied

**Short description of the study population**

All patients who developed influenza-like symptoms and who are considered to be epidemiologically linked by time, place, and exposure to a probable or confirmed avian influenza or human pandemic influenza case (in poultry, wild birds, animals or humans). In addition, patients with documented seroconversion (positive serological test in a national, regional or international influenza laboratory whose test results confirm infection with avian influenza), who either remain asymptomatic or experience only mild illness will be eligible for inclusion. All cases identified in the literature, by treating physicians and other health care providers or by local government or international agencies will be pursued for inclusion in the registry.

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**Age groups**

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

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**

Other

**Special population of interest, other**

Patients infected with avian influenza A (H5N1)

**Estimated number of subjects**

647

## Study design details

**Outcomes**

survival, discharge from hospital with serious impairments

**Data analysis plan**

Analyses are primarily descriptive. Relative risks are used to compare survival in patients receiving antivirals and other treatments compared to those who did not receive those treatments, and to understand the impact of various effect modifiers and potential confounders. Multivariate modeling may be used to examine the relationship between survival and a variety of clinical and epidemiologic factors. Multiple imputation may be used for important missing data.

## Documents

**Study publications**

Adisasmito W, Chan PK, Lee N, Oner AF, Gasimov V, Aghayev F, Zaman M, Bamgboye …

Oner AF, Dogan N, Gasimov V, Adisasmito W, Coker R, Chan PK, Lee N, Tsang O, Ha…

Chan PK, Lee N, Zaman M, Adisasmito W, Coker R, Hanshaoworakul W, Gasimov V, On…

Zaman M, Ashraf S, Dreyer NA, Toovey S. Human infection with avian influenza vi…

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# 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 sources (types)**

Disease registry

Other

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**Data sources (types), other**

Prospective patient-based data collection, Medical record review; published case studies with detailed patient data; case data from national public health

agencies

## 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