

# Assessment of the immunogenicity and safety of the Northern Hemisphere 2010/2011-season influenza vaccine in elderly and young subjects according to European Medicines Agency (EMA) regulations

<b>Submission date</b> 12/05/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 21/01/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/02/2023	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

INF-V-A004

## Study information

**Scientific Title**

Assessment of the immunogenicity and safety of the Northern Hemisphere 2010/2011-season influenza vaccine in elderly and young subjects according to European Medicines Agency (EMA) regulations: an open label, non-randomised uncontrolled safety and efficacy study

**Study objectives**

The Northern Hemisphere 2010/2011-season influenza vaccine fulfills the European Medicines Agency (EMA) requirements for re-registration of influenza vaccines.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Local Medical Ethics Committee (Ethikkommission beider Basel [EKBB]), Switzerland, approved on the 21 April 2010

**Study design**

Open non-randomised uncontrolled safety/efficacy study

**Primary study design**

Interventional

**Study type(s)**

Prevention

**Health condition(s) or problem(s) studied**

Influenza

**Interventions**

Biological: single dose of trivalent virosomal adjuvanted influenza vaccine (Inflexal® V). Total duration of follow-up: approximately three weeks.

**Intervention Type**

Biological/Vaccine

**Phase**

Not Applicable

**Primary outcome(s)**

Immunogenicity, assessed by haemagglutination inhibition test; blood to be collected before, one, two and approximately three weeks after vaccination.

**Key secondary outcome(s)**

Safety, assessed at baseline and at three weeks after vaccination, including a four-day adverse event questionnaire, soliciting a set of local and systemic adverse events (AEs) according to the European Medicines Agency (EMA) specifications.

**Completion date**

31/07/2010

# Eligibility

## Key inclusion criteria

1. Healthy female and male volunteers equal to or older than 18 years of age on the day of enrolment
2. Written informed consent

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

All

## Key exclusion criteria

1. Pregnancy and lactation
2. Serious adverse reaction to any influenza vaccine

## Date of first enrolment

01/06/2010

## Date of final enrolment

31/07/2010

# Locations

## Countries of recruitment

Switzerland

## Study participating centre

Covance Clinical Research Unit AG

Allschwil

Switzerland

4123

# Sponsor information

**Organisation**

Crucell Switzerland AG (Switzerland)

**Funder(s)****Funder type**

Industry

**Funder Name**

Crucell Switzerland AG (Switzerland)

**Results and Publications****Individual participant data (IPD) sharing plan**

Not provided at time of registration

**IPD sharing plan summary**

Not provided at time of registration