Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial:** Phase 1 Evaluation of the Safety and Immunogenicity of a Replication-competent Adenovirus Serotype 4-vectored H5N1 Influenza Candidate Vaccine – Ad4-H5-Vtn

**Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):** ClinicalTrials.gov

**Authors/sponsors:** Kenneth Kelley, Dr. Marc Gurwith/Pax Vax

**Study Design (including the phase of clinical trial):** Phase 1, ascending dosage, double blind, placebo controlled

**Vaccine subtype:** H5  
**Virus:** Vietnam/1194  
**Manufacturer:** Pax Vax, USA

**Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector):** Gene of hemagglutinin for strain “Vietnam 1194” incorporated into replication competent Adenovirus type 4

**Adjuvant:** None

**Delivery system/site:** Oral

**Doses (antigen and adjuvant, number of doses, intervals between administrations):** \(10^7\), \(10^8\) and \(10^9\) viral particles per dose, Two doses at day 0 and 56

**Study population:**  
**Number of subjects involved:** 101  
**Age range:** 23-31  
**Health status:** Healthy volunteers

**Special inclusion/exclusion criteria:** Exclusions: Health care worker in contact with immunodeficient patients; child care worker in contact with children < 5; lives with anyone age < 18 or > 65, or immunodeficient

**Clinical Endpoints Assessed**

**Safety assessments:** Adverse events; 7 day reactogenicity diaries; clinical laboratory; PCR of blood and throat swabs for evidence of systemic spread of Ad4 vaccine virus

**Immunogenicity assessments:**

- **immunoassay type:** Ad4 neutralization antibody
- **HI (type of RBC used):** Horse
- **NT (type of neutralization assay):** TBD
- **SRH**

**Results**

**Safety:**

**Reactogenicity:**

- AEs:
- SAEs:
  - No serious AEs, no related severe AEs, no significant laboratory abnormalities
  - 7 day reactogenicity diaries – mild GI/respiratory symptoms
  - Evidence of transmission to 3 HHCs
  - No systemic spread of vaccine virus

**Immunogenicity**

- **HI**
Per cent responders in HAI after one and two doses

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**SRH:**
Per cent with titre (in mm²)  None

**Current status of the clinical trial (completed, ongoing, in preparation):**  On going

**Date envisaged for availability of results, if not yet available:**  Dec 31, 2010

**Planned time schedule for next phase of development:**  Phase 2 challenge study (protection against attenuated H5N1) early 2011