Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial**: The phase II clinical trial of influenza inactivated adjuvanted split vaccine in adult volunteers

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

**Authors/sponsors**: Margarita Xydia-Charmanta, International Federation of Pharmaceutical Manufacturers & Associations

**Study Design**: Phase II, open label clinical trial in adults

**Vaccine**: H5N1  **Strain**: /Indonesia/5/2005

**Manufacturer**: The Chemo-Sero-Therapeutic Research Institute (KAKETSUKEN), Japan

**Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector)**: Inactivated split virus propagated in EB66 cells

**Adjuvant**: AS03

**Delivery system/site**: Two intramuscular injections at day 0 and 21

**Doses (antigen and adjuvant)**: 15ug per dose

**Study population**: 369 volunteers

**Age range**: 20 – 64 years  **Health status**: Healthy

**Specific inclusion/exclusion criteria**:

**Clinical Endpoints Assessed**:

**Safety assessments**: Systemic and local reactions

**Immunogenicity assessments**: Hemagglutination inhibition assay

**Results**:

**Safety**: Vaccine was assessed as well tolerated and safe

**Immunogenicity**

GMTs :

**GMT Ratios (post:pre)**:

Fold increase in HI after 2 doses;

43.73  

(3.75ug + AS03)

**Per cent responding (4 fold or greater rise and definition for reporting)**:

≥4 fold increase after 2 doses;

100%  

(3.75ug + AS03)

**Per cent responders at specified tite**:
HI ≥40 after two doses;
100% (3.75 ug + AS03)

Others assays: none

Status of trial (ongoing/completed): Completed in 2013