Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: Development of human influenza H5N1 vaccine in Japan
Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov)
Authors/participants/sponsors: Denka Seiken Co.LTD,
Project is being supported by the Government of Japan, NIID, NIBIO and National Licensing Agency

Study Design: 150 healthy adults per group, total 300 adults, 2 doses on days 0 and 21 with subcutaneous application (Phase II/III).
Vaccine: Egg grown, formalin inactivated, adjuvanted H5N1
Manufacturer: Denka Seiken Co.LTD, Japan
Type: Whole virus, vaccine strain A/Vietnam/1194/2004
Adjuvant: Al(OH)3
Delivery system/site: subcutaneously
Doses (antigen and adjuvant): 5 or 15 µg of viral HA protein with 0.15 mg of Al(OH)3

Study population: Age range: Adults, 20-64 years old
Health status: Health
Special inclusion/exclusion criteria:

Clinical Endpoints Assessed: Safety clinical laboratory tests (blood, urine), clinical signs and symptoms, physical checkup (body temperature, blood pressure, pulse rate, ECG)

Safety assessments:
Immunogenicity assessments: antibody responses were measured at days 0, 21 and 42
Immunoassay type: hemagglutination and neutralization
HI (type of RBC used) Horse RBCs
Neutralization (type of neutralization assay): microneutralization

Results
Safety: No data available
Reactogenicity:
AEs
SAEs:

Immunogenicity: No data available
GMVs
GMV Ratios (post:pre)
Per cent responding (4 fold or greater rise and definition for reporting)
Per cent responders at titre ≥ 40

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

Date envisaged for availability of results if not yet available :

Planned time schedule for next phase of development