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: 20 healthy male adults per group, total 120 adults; 2 doses on days 0 and 21 with intramuscular and subcutaneous application (Phase I).
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, intramuscular
  Doses (antigen and adjuvant):
    1.7 µg of viral HA protein with 0.05mg of Al(OH)3
    5 or 15 µg of viral HA protein with 0.15mg of Al(OH)3

Study population: Age range: Adults, 20-40 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
    GMTs
    GMT 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