Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial:** A Phase II/III clinical trial to assess safety and immunogenicity of the Pandemic influenza vaccine (Human, live attenuated) A (H1N1) 2009 of SIIL In Adults, Elderly and Pediatric Populations.

**Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):** CTRI/2010/091/000092 ([http://www.ctri.in/](http://www.ctri.in/))

**Authors/sponsors:** Prasad Kulkarni/ Serum Institute of India Ltd

**Study Design (including the phase of clinical trial):** Phase II/III double-blind randomized, Placebo-controlled clinical trial

**Vaccine subtype:** H1N1 pandemic Virus: A/California/7/2009 (H1N1)v virus

**Manufacturer:** Serum Institute of India Ltd

**Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector):** Live attenuated vaccine

**Adjuvant:** None

**Delivery system/site:** Intranasal spray

**Doses (antigen and adjuvant, number of doses, intervals between administrations):** 10^7.0EID50/05 ml, two doses of 0.5 ml on day 0 and 21.

**Study population Number of subjects involved:** 330 **Age range:** 3yrs and above

**Health status:** Healthy children (≥ 3-17 yrs), adults (≥ 18-49 yrs) and Elderly (≥ 50 yrs)

**Special inclusion/exclusion criteria:**

**Subject inclusion criteria**
Normal healthy subjects of appropriate age (pediatric 3-17 years; adult 18-49 years; elderly ≥ 50 years), willing to give consent and willing to comply with study protocol, Free of obvious health problems and agreeing for birth control measures.

**Subject exclusion criteria**
known allergy to eggs or other components of the vaccine, pregnancy, lactation, participation in other clinical trial, Chronic administration of immunosuppressants, Acute febrile illness or acute infectious disease, nasal pathology, Major congenital defects or serious chronic illness, History of H1N1 infection or influenza vaccination, Receipt of licensed vaccine, sera and/or any blood products, intra-nasal medication, history of GBS, Acute or chronic, disease of any system

**Clinical Endpoints Assessed**
**Safety assessments:** Vitals, solicited local and systemic reactions within 7 days, adverse events in 42 days and SAEs in 90 days.

**Immunogenicity assessments:** Haemagglutination Inhibition (HI), Micronutralisation (MN), Serum IgG and Mucosal IgA on Day 0, 21 and 42.

**Results:**
**Safety:** Awaited
**SAEs:** None.

**Immunogenicity:** sample under testing

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

**Date envisaged for availability of results, if not yet available:** 1 May 2010

**Planned time schedule for next phase of development:** Post licensure studies