**Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:**

**Title of Trial:** A Double-Blind, Randomized Phase 1b Study of the Safety and Immunogenicity of a Prime-Boost Schedule of the 2011/12 Investigational DNA Trivalent Influenza Vaccine, VRC-FLUDNA061-00-VP, Followed by the 2012/13 Seasonal Influenza Trivalent Inactivated Vaccine (TIV) Compared to 2012/13 TIV Alone in Healthy Adults Ages 18-50 and 51-70 Years

**Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):** NCT01498718

**Authors/sponsors:** Dr. Julie Ledgerwood (Protocol Chair), Dr. Barney Graham, VRC/NIAID/NIH, USA

**Study Design (including the phase of clinical trial):** VRC 701 is a Phase 1b, randomized study in healthy younger (18-50 years) and older (51-70 years) adults. For each age group the study will evaluate the safety, tolerability, and immunogenicity of a prime-boost vaccination regimen against the seasonal influenza virus with an investigational plasmid DNA vaccine directed towards the 2011/12 influenza vaccine strains as a prime followed 36 weeks later by the 2012/13 influenza trivalent inactivated vaccine (TIV) boost, as compared to placebo prime followed by the 2012/13 seasonal TIV. Equal numbers of healthy adults will receive the DNA vaccine or a control injection with phosphate buffered saline as the first injection.

**Vaccine subtype:** Prime/boost DNA vaccine and inactivated virus vaccine

**Virus:** DNA plasmid encoding 2011-2012 seasonal strains and inactivated vaccine encoding trivalent 2012/13 seasonal strains

**Manufacturer:** DNA vaccine - NIH, USA; inactivated vaccine – Sanofi Pasteur, Inc

**Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector):** DNA vaccine and inactivated virus

**Adjuvant:** None

**Delivery system/site:** IM by Biojector for DNA vaccine and IM by needle/syringe for inactivated vaccine

**Doses (antigen and adjuvant, number of doses, intervals between administrations):** DNA vaccine – 4000 μg, inactivated vaccine - 45μg

**Study population:** Adults

**Number of subjects involved:** 131

**Age range:** 18-70 years old

**Health status:** Healthy volunteers

**Special inclusion/exclusion criteria:** None

**Clinical Endpoints Assessed:**

The primary objectives are to evaluate the safety and tolerability of the investigational prime-boost regimen. Secondary and exploratory objectives are related to the humoral and cellular immune responses

**Safety assessments:**

- Local reactogenicity signs and symptoms
- Systemic reactogenicity signs and symptoms
- Laboratory measures of safety
- Adverse and serious adverse experiences

**Immunogenicity assessments (immunoassay type):**

- HI (type of RBC used): HAI assay using horse erythrocytes
- NT (type of neutralization assay): ?
- SRH: Not done

**ELISpot:** to determine frequency of T cells producing IFN-γ in response to pools of overlapping peptides representing influenza antigens
ICS: to determine frequency of CD4+ and CD8+ cells that produce IL-2 or IFN-γ in response to pools of overlapping peptides representing influenza antigens

Results:

Safety: The prime vaccine was safe and well tolerated