Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Tittle of Trial:** An Open-Label, Dose-Escalation, Phase I Study of the Safety, Tolerability and Immunogenicity of the Prime-Boost Regimen of the Investigational 2012/13 Seasonal Influenza DNA Vaccine, VRCFLUDNA063-00-VP, Followed by the 2012/2013 Seasonal Influenza Trivalent Inactivated Vaccine (TIV) Compared to TIV Prime-TIV Boost in Children and Adolescents Ages 6-17 Years

**Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):** NCT01609998

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

**Study Design (including the phase of clinical trial):** VRC 702 is a Phase I, dose escalation study in healthy adolescents and children (6-17 years) to evaluate the safety, tolerability, and immunogenicity of a prime-boost regimen of the 2012/2013 seasonal influenza DNA vaccine (HA DNA) followed by licensed 2012/2013 TIV. The comparator groups will receive licensed 2012/2013 TIV as prime and boost. The groups in this study are defined by age and prime vaccine received and the older age group will the first to receive each dose of the HA DNA vaccine

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

**Virus:** DNA plasmid and inactivated vaccine encoding 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 – 1000 μg, 4000 μg , inactivated vaccine - 45μg

**Study population:** adolescents and children

**Number of subjects involved:** 70

**Age range:** 6-17 year 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:**