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

**Title of Trial**: A Phase II Randomized, Partially-Blinded, Controlled Trial in Healthy Adults Aged 65 Years and Older to Assess the Safety, Reactogenicity, and Immunogenicity of an MF59-Adjuvanted, Monovalent Inactivated Influenza A/H7N9 Virus Vaccine Administered Intramuscularly at Different Intervals and Dosages

**Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov)**: NCT02213354

**Authors/sponsors**: National Institute of Allergy and Infectious Diseases (NIAID)

**Study Design**: Phase II, randomized, double blind

**Vaccine**: H7N9  
**Manufacturer**: Sanofi Pasteur  
**Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector)**: Inactivated split  
**Adjuvant**: MF59  
**Delivery system/site**: Intramuscular injection

**Doses (antigen and adjuvant):**

Experimental: Group 6  
60 subjects receive Sanofi A/H7N9 antigen 15 mcg plus Novartis MF59 adjuvant IM on Day 1, Day 57, and Day 169

Experimental: Group 5  
60 subjects receive Sanofi A/H7N9 antigen 15 mcg plus Novartis MF59 adjuvant IM on Day 1, Day 29 and Day 169

Experimental: Group 2  
60 subjects receive Sanofi A/H7N9 antigen 3.75 mcg plus Novartis MF59 adjuvant IM on Day 1, Day 57, and Day 169

Experimental: Group 3  
60 subjects receive Sanofi A/H7N9 antigen 7.5 mcg plus Novartis MF59 adjuvant IM on Day 1, Day 29 and Day 169

Experimental: Group I  
60 subjects receive Sanofi A/H7N9 antigen 3.75 mcg plus Novartis MF59 adjuvant intramuscularly (IM) on Day 1, Day 29 and Day 169

Experimental: Group 4  
60 subjects receive Sanofi A/H7N9 antigen 7.5 mcg plus Novartis MF59 adjuvant IM on Day 1, Day 57, and Day 169

**Study population**: 600 volunteers,

**Age range**: 65 years and older  
**Health status**: Healthy

**Specific inclusion/exclusion criteria:**
1. Provide written informed consent prior to initiation of any study procedures.  
2. Are able to understand and comply with planned study procedures and be available for all study visits.  
3. Are males or females, 65 years of age and older.
4. Are in good health.
   5. Oral temperature is less than 100.0 degrees F.
   6. Pulse is 50 to 115 bpm, inclusive.
   7. Systolic blood pressure is 85 to 160 mm Hg, inclusive.
   8. Diastolic blood pressure is 55 to 95 mmHg, inclusive

**Clinical Endpoints Assessed:**

**Safety assessments:**
- Occurrence of study vaccine-related serious adverse events from the time of the first study vaccination through approximately 12 months after the last study vaccination
- Occurrence of solicited injection site and systemic reactogenicity events from the time of each study vaccination through 8 days after each study vaccination

**Immunogenicity assessments:**
- Percentage of subjects achieving a serum HAI antibody titer of 1:40 or greater against the A/H7N9 antigen contained in the study vaccine at approximately 28 days after the second study vaccination [Time Frame: 28 days after the second study vaccination]
  - Percentage of subjects achieving HAI seroconversion (defined as either a pre-vaccination HAI titer <1:10 and a post-vaccination HAI titer >/=1:40 or a pre-vaccination HAI titer >/= 1:10 and a minimum four-fold rise in post-vaccination HAI antibody titer) [Time Frame: 28 days after the second study vaccination]

**Results:** Not yet available

**Safety:**

**Immunogenicity**

**GMTs:**

**GMT Ratios (post:pre):**

**Per cent responding (4 fold or greater rise and definition for reporting):**

**Per cent responders at specified tite:**

**Others assays:**

**Status of trial (ongoing/completed):** 2014-2017, ongoing