Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial**: Evaluation of safety and immunogenicity of seasonal influenza vaccine in children

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

**Authors/sponsors**: Sanofi Pasteur

**Study Design**: Phase II randomized, placebo-controlled

- **Vaccine**: Seasonal vaccine containing the following strains: A/Brisbane/59/2007 (H1N1), A/Brisbane/10/2007 (H3N2), B/Brisbane/60/2008 (B)
- **Manufacturer**: Sanofi Pasteur
- **Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector)**: Inactivated split virus
- **Adjuvant**: None
- **Delivery system/site**: Intramuscular application, single dose

**Doses (antigen and adjuvant)**: 15µg of each vaccine strain
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**Study population**: 796 children of 6 to 17 years

**Age range**: Health status:

**Specific inclusion/exclusion criteria**:

**Clinical Endpoints Assessed**:

- **Safety assessments**:

**Results**:

- **Safety**: Vaccine is safe and well tolerated

**Immunogenicity**

- **GMTs**:

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

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

**Per cent responders at specified tite**:

- HI≥40 after 1 dose with antigens:
  - TIV: 94% vs Placebo 54%, H1N1 seasonal
  - H3N2: 96% vs 64%
  - B: 70% vs 15%
51% 47% H1N1 pandemic

Others assays:

Status of trial (ongoing/completed): Completed