Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial:** Clinical evaluation of safety and immunogenicity of H1N1 influenza vaccine in children

**Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):** H1N1-009 (GSK registration No)

**Authors/sponsors:** Dr D.Compens

**Study Design:** Phase I-II randomized trial

**Vaccine:** H1N1

  - **Manufacturer:** GSK
  - **Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector):** Inactivated split vaccine containing the strain A/California/07/2009
  - **Adjuvant:** AS03
  - **Delivery system/site:** Intramuscular injection

**Doses (antigen and adjuvant):** 1.9 or 3.75µg per dose

**Study population:** 102 children of 6-35 months of age

  - **Age range:** Healthy
  - **Specific inclusion/exclusion criteria:**

**Clinical Endpoints Assessed:**

  - **Safety assessments:**
  - **Immunogenicity assessments:**

**Results:**

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>1 dose</th>
<th>2 doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>25%</td>
<td>40%</td>
</tr>
<tr>
<td>Redness</td>
<td>20%</td>
<td>28%</td>
</tr>
<tr>
<td>Swelling</td>
<td>17%</td>
<td>21%</td>
</tr>
</tbody>
</table>

Vaccine was safe and well tolerated

**Immunogenicity**

**GMTs :**

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

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

- HI≥4 fold increase after one dose:
  - 6-35m
  - 98% (1.9µg+AS03)
  - 98% (3.75µg+AS03)

**Per cent responders at specified tite :**

- HI≥40 after one dose:
### Others assays:

<table>
<thead>
<tr>
<th>Time</th>
<th>Status</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-35m</td>
<td>100%</td>
<td>(1.9µg+AS03)</td>
</tr>
<tr>
<td>100%</td>
<td>(3.75µg+AS03)</td>
<td>&quot;</td>
</tr>
</tbody>
</table>

**Status of trial (ongoing/completed):** Completed in 2009