Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial:** Evaluation of seasonal influenza vaccine in Indonesia

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

**Objective:** To evaluate the safety and immunogenicity of seasonal influenza vaccine produced in Indonesia in adults.

**Authors/sponsors:** BioFarma, Indonesia; Biken, Japan

**Study Design:** Phase II experimental, randomized, single blind

**Vaccine:** Seasonal containing the following strains: "A/Brisbane/59/2007 (H1N1)
A(Uruguay/716/2007 (H3N2), B/Brisbane/60/2008 (B)

**Manufacturer:** BioFarma, Indonesia

**Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector):** Eggs-derived inactivated split virus

**Adjuvant:** None

**Delivery system/site:** Intramuscular injection, Single dose

**Doses (antigen and adjuvant):** 15µg of each vaccine strain

**Study population:** 60 adults of 12-65 years old

**Age range: Health status:** Health volunteers

**Specific inclusion criteria:**
- Subjects 18 years of age and older in good health as determined by medical history, physical assessment and clinical judgement of the investigator and without influenza within the past 6 months.

**Clinical Endpoints Assessed:**

**Safety assessments:**

**Immunogenicity assessments:**

**Results:**

**Safety:**

**Immunogenicity**

**GMTs :**

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

<table>
<thead>
<tr>
<th>Vaccine Strain</th>
<th>GMT Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>H1N1</td>
<td>13.0</td>
</tr>
<tr>
<td>H3N2</td>
<td>15.3</td>
</tr>
<tr>
<td>B</td>
<td>15.6</td>
</tr>
</tbody>
</table>

Per cent responding (4 fold or greater rise and definition for reporting):
≥4 fold increase in HI after one dose:
76% H1N1
85% H3N2

Per cent responders at specified tite:
"HI≥40 after one dose:
100% H1N1
100% H3N2
100% B"

Others assays:

Status of trial (ongoing/completed): Completed