Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial:** Clinical evaluation of a novel recombinant influenza vaccine candidate

**Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):** FLU-v 001

**Authors/sponsors:** Dr Wilson Caparrós-Wanderley, CSO

**Study Design:** A single centre, randomised, double blind, phase I study of the safety, tolerability and immunogenicity of a single S/C dose of FLU-v,

**Objectives:**
To determine the safety and tolerability of two different dose levels of FLU-v
To determine the effect of the adjuvant on the safety and tolerability of FLU-v
To determine the immunogenicity of FLU-v with and without adjuvant

**Vaccine:** Recombinant

**Manufacturer:** SEEK, UK

**Type (whole virus/subvirus/subunit/live/recombinant/DNA/vector):** Admixture of 4 synthetic polypeptides relevant to regions of M1, M2 and NP

**Adjuvant:** ISA-51 or none

**Delivery system/site:** Subcutaneous injection

**Doses (antigen and adjuvant):** 250 µg or 500 µg per dose, single dose

**Study population:** 40 adults

**Age range:** Healthy volunteers

**Health status:** Healthy volunteers

**Specific inclusion/exclusion criteria:**

**Clinical Endpoints Assessed:**
Enrolment: Healthy males (age 18-45, BMI 18.5-28.5); non-smokers, no history of Flu-like disease (3 months) or Hepatitis.

**Safety assessments:**

**Immunogenicity assessments:**

**Results:**

**Safety:**
- FLU-v with adjuvant induces a vaccine specific T cell response
- FLU-v without adjuvant does not induce a specific T cell response

**Immunogenicity:**
- FLU-v with or without adjuvant does not induce a specific B cell response
- FLU-v with adjuvant induces a vaccine specific T cell response
- FLU-v without adjuvant does not induce a specific T cell response

**Status of trial (ongoing/completed):** Completed in 2011