Reviewer's report

Title: A randomized, controlled non-inferiority trial comparing H1N1 2009 pandemic vaccine antigen, with and without AS03 adjuvant system, co-administered or sequentially administered with an inactivated trivalent seasonal influenza vaccine

Version: 2 Date: 4 June 2012

Reviewer: Zol Vaj

Reviewer's report:

The authors responded to some issues raised by the reviewers and argued with others. Importantly, they have made some improvements regarding CONSORT compliance. They have also included at least some weaknesses and limitations of their study.

Specific comments:

The authors state and emphasize repeatedly that they had worked with "only adults less than 40 years of age without a history of receiving TIV to work with a more influenza naive population" - Being "influenza naive" is not defined by age or a previous history of TIV administration, but by pre vaccination HA titers. It appears that up to 25% of the subjects were seroprotected at baseline already. Thus, I don't think the points on "influenza naive" can be made.

Please provide p values for safety and reactogenicity comparisons.

Were the sera tested independently to confirm the results? There are known issues with the high inter-laboratory variation of HA assays.

Can the authors provide microneutralization results for immunogenicity?

Discussion section: "Grade 3 pain injectin(sic) site pain" - Rephrase this.

"Neither the subjects or(sic) study personnel evaluating evaluating the safety and immunogenicity were aware of vaccine assignments" - how was blinding maintained if the adjuvanted and non-adjuvanted vaccines had a different appearance?

"Study vaccine not administered N=260" - please provide reasons for this.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published
**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

'I declare that I have no competing interests