Reviewer's report

Title: International Active Surveillance Study of Women Taking Oral Contraceptives (INAS-OC Study)

Version: 4 Date: 7 October 2009

Reviewer: Kavita Nanda

Reviewer's report:

This is an important and timely study.
I feel that the authors have addressed all my previous concerns adequately and thoroughly, and made appropriate changes and clarifications to the manuscript. They have also clarified the purpose of the study (required by FDA).
I still feel that the manuscript's statistical issues should be reviewed by a statistical reviewer, to assure that their proposed statistical methods are appropriate.
A new comment is that they do need to update the background section in view of the recently published studies on drospirenone-containing COCs and VTE.