Reviewer's report

Title: Protocol for Homeopathic Drug Proving Trial

Version: 2 Date: 24 March 2010

Reviewer: Gordon Doig

Reviewer's report:

This is a very interesting and novel protocol. Please address the following issues:

Please include the name of the drug to be evaluated in the Title. Please indicate this is a Phase I clinical trial in the Title and Abstract.

The Background should not serve as a discourse on the history of HDP.

Please focus on the drug to be tested, its chemical composition, previous evidence of benefit and justification for current trial.

At the end of the Background, please state the specific hypothesis to be tested. For example: Past evidence suggests Drug X has shown benefit for Disease A in gerbils, we therefore believe it is likely to have an effect in Disease A and perhaps Disease B, since both are similar. If you do not have an a priori hypothesis, please emphasize throughout your Protocol that any results generated by your Phase I trial are to be viewed as hypothesis generating.

With regards to analysis, please explicitly report all baseline values that are to be examined for balance. How will it be decided whether a baseline value will be included in the adjusted ANCOVA? Will baseline univariate p-values for baseline values be used to assess balance?

Please provide your details.

The Discussion should not serve as a discourse on the history of the HDP and its juxtaposition with GCP. Please simply focus on the unique aspects of your clinical trial that merit further comment.