

# NEED FOR AND MODIFICATIONS IN CLINICAL TRIAL METHODOLOGY FOR EVALUATION OF INDIGENOUS TREATMENTS/MEDICINAL DRUGS

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As pointed out often on evaluating complementary treatments, 'clinical trials are the best way of assessing the efficacy of treatments but not in their present form'. The need is felt because many indigenous drugs even if found clinically useful, not proved to be significantly so in 'clinical trials'. This need is highlighted and few possible modifications while applying classical clinical trial methodology (for evaluation of indigenous treatments/medicinal drugs, suggested on the basis of difficulties realized in the field) are discussed. They include:

- Equivalence trial against an usual superiority trial.
- Use of evidence based randomization in adaptive allocation while applying 'play the winner rule'
- Zelens type [A new design for randomized clinical trials, New Engl. Jr. Med. Vol, 300 : 1242-1245 (1979)] modification to reduce 'placebo effect'

First suggestion is already incorporated in Center's forthcoming trial. The remaining will be tested/implemented in a specifically planned project. However, purpose of this presentation is to add few more in the list (on the basis of discussion/your suggestions) & authenticate the proposed ones, which are argued here considering many possible counter-arguments.