

## CLINICAL TRIAL EVALUATION CHECKLIST

### I. Awareness

- A. It is important to realise that a single report of a clinical trial offers only one viewpoint. To appreciate its merits you need to be aware of other work done in the area.
- B. The clinical trial is necessarily restricted by design so that you need to appreciate the design when thinking about drawing general conclusions.
- C. All authors will tend to minimise the problems with their work. This is quite natural. It is up to the reader to be prepared to read between the lines in order to understand what really happened.

### II. Aims

- A. Is the purpose of the study defined?
- B. Is the main endpoint of the study defined?

### III. Design

- A. What was the design of the study (randomised, double-blind, parallel, cross-over, etc)?
- B. If this is a cross-over trial, is the washout period between treatments appropriate?
- C. What was the power to detect a treatment effect?
- D. Was the study long enough to follow the response adequately?

### IV. Subjects

- A. Was the study reviewed and approved by an Ethical Committee or Institutional Review Board?
- B. Are subject selection criteria reasonable (inclusion, exclusion)?
- C. Are the groups of subjects in the treatment groups comparable?
- D. Are all the subjects accounted for (dropouts, withdrawals)?
- E. What proportion of eligible subjects were actually enrolled in the trial?

### V. Treatments

- A. Medicine
  - 1. What was the treatment that was being tested?
  - 2. How was the dose selected?
  - 3. How was compliance with treatment checked?
- B. Control
  - 1. What was the control group?
  - 2. Was the control group appropriate?

### VI. Observation Methods

- A. What methods were used to measure responses?
- B. Are each of the methods fully described (or referenced)?

- C. Can you understand the methods? If not what could the authors have done to make it easier?

## VII. Analysis Methods

- A. How were the results analysed (intention to treat, as-treated)?
- B. Can you identify the statistical methods used to support the Results?
- C. Can you understand the methods? If not what could the authors have done to make it easier?

## VIII. Consistency

- A. Check for internal consistency of results in graphs and tables. If you can find inconsistencies then this means the authors were not very careful in writing the report and may not have been careful in performing the study.

## IX. Interpretation

- A. Are the results statistically significant?
- B. Are the results clinically important?
- C. If the trial has “negative” results (ie. no significant differences) has an attempt been made to indicate the size of difference that could have been detected if it did in fact exist? (*post hoc* power analysis)
- D. Did the trial lead to knowledge about how to individualise treatment?

## Further Reading

Nies AS, Spielberg SP. Chapter 3: Principles of therapeutics. Goodman & Gilman's *The Pharmacological Basis of Therapeutics* 1995; (9th Edn) 43-62