Reviewer’s report

Title: Developing a guideline for clinical trial protocol content: Delphi consensus survey

Version: 1 Date: 5 July 2012

Reviewer: Anthony Jorm

Reviewer’s report:

• Major Compulsory Revisions
  None

• Minor Essential Revisions
  The size of the item pool rated by the panel needs to be stated in the Abstract. This is helpful in interpreting the number of concepts (63) rated as of high importance.

  I was initially confused by the sentence in the Abstract referring to “lower quartile”. This only became clear when I realized it referred to the inter-quartile range. This could be reworded to make it very clear to the reader.

  On page 7, more detail needs to be given explaining how the panelists were asked for comments, revisions and nominations of new items. What exactly were the instructions and how was this information used to generate additional items?

  The top of p. 8 refers to “consistency of ratings”. I don’t think this is quite the right terminology. There would be consistency if all the panelists gave ratings of 5, which is not what the term is intended to cover.

  It is unclear why the ratings for Parts 4 and 5 were changed from 1-10 to a 3-point scale (include, exclude, unsure).

  The top of p. 13 refers to “this variation”. What variation is being referred to is not immediately clear.

  Page 13, paragraph 2, sentence 2: try to get rid of the double negative.

  Page 13, final paragraph: it is not clear what is the distinction between “Delphi success” and “validity”.

  Table 1: make “triallists” singular to be consistent with the other variables.

  Table 2: “minimum” occurs twice in the legend.

• Discretionary Revision
  None

Level of interest: An article of importance in its field
Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests