Reviewer's report

Title: Random Allocation Software

Version: 1  Date: 1 September 2004

Reviewer: damian mcentegart

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General
I believe this software is a useful addition to the current software that is currently freely available. But I would like to see the advantages and validity of the software discussed more extensively so that the reader is clearly informed.

The article is understandable but the punctuation and grammar could be improved. In this respect, the article would benefit from a further review by a suitable person.

I am sure these points could be addressed without too much work.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)
1 The testing of the product should be detailed. What confidence can the reader have that the files produced are valid? Is the random number generator used reliable?

2 The advantages of the program should be more extensively discussed and include more discussion of the limitations of the other products available. If the advantages are clear to the reader then he/she will not have to examine the other products; the readers are not going to be randomisation software experts. This shouldn’t be too much effort -just a few sentences in the appropriate places. For instance what is the advantage of having flexible UIs-I know it’s a big advantage but does the reader? In terms of the limitations of other products I tried randomization.com and found it very simple to use-the disadvantage is that the output has to be saved as a html file and the UIs must be sequential. But the very brief summary implies that this software cannot produce UIs.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)
3 The punctuation and grammar need some attention. For instance the use of commas, would help the readability. There are a number of grammatical errors relating to apostrophes and plurals e.g. the plural of software is not softwares, verb tense and usage is sometimes incorrect “will be intended”, “different types …..includes”. Unfortunately there are too many of these trivial errors to list and I recommend the author asks a suitable colleague to review his text.

4 Any limitations of the software should be briefly discussed (“almost all of these problems have been addressed”-which haven’t?). Can crossover trials be handled? Can a stratified permuted blocks list be produced?

5 The abstract implies sealed envelopes is a randomisation method which it isn’t. It is a way of
implementing a randomisation scheme which still has to be generated.

6 The list of other software has a complete correspondence with Martin Bland’s website and this should be acknowledged and referenced as a convenient summary of this software is given there.

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Discretionary Revisions (which the author can choose to ignore)
7 Lachin and Rosenberger’s book “Randomisation in Clinical trials Theory and Practice” could perhaps be used as a general reference and possibly to reference some of the concepts. e.g. the shuffled allocation technique is equivalent to the random allocation rule described therein. Similarly the book would give a reference for mixed random blocks

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: No

Declaration of competing interests:

Theoretically there could be a conflict of interest as my Company provides randomisation schemes as part of its general service of providing an Interactive Voice Response service for clinical trials. But this is only one component of the Company’s service. Furthermore the service is primarily provided to the pharmaceutical industry who would not generally use software that has not been validated to FDA 21 CRF Part 11 standards. Thus in practical terms the conflict of interest is nil.