Reviewer's report

Title: Using a Business Model Approach and Marketing Techniques for Recruitment to Clinical Trials

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Reviewer: Ursula Bowler

Reviewer's report:

1 Does it address an important or timely issue?

Recruitment to trials is an on-going concern for RCTs and well designed studies. The business model recommended by the authors is another tool to assist in the management of trials. However any tool is only as good as the craftsman in whose hands it is used. From their own admission while this model worked well with their first case study it was not as successful in the third which would suggest either a lack of understanding or ability in the later group or an extremely experienced team in the former or both.

Funding for trials is likely to be more competitive in the coming years which increased the imperative to deliver trials on time and within budget. The first case study demonstrates that this model was used effectively to run a large multinational trial. This would suggest the model is sound but the experience within this trial co-ordinating centre would have the knowledge to be able to put the theory into practice.

In the section on ‘Further research required’ the authors suggest the development of a manual or similar tool to operationalise the model consistently, it would also be an extremely useful guide and learning tool for less experienced groups who are working independently or within newly developing CTUs.

2. Is it well reasoned?

Case study 1 demonstrating the effectiveness of this tool during the planning and set up of a study is well made and the most convincing. The use of this tool for diagnostic and audit purposes is not as clear cut however the publication of this paper may encourage other groups to validate the model applying it to their own trials. Feedback to the authors should be encouraged to confirm or refute the usefulness of this tool in these alternative roles.

3. Is it relatively balanced, or does it make plain where the author's opinions might not represent the field as a whole?

The authors are realistic about the papers limitations, as highlighted in the ‘Strengths and weaknesses’, recruitment into TXT2STOP may have picked up anyway as the normal pattern of recruitment is a slow start with a rapid increase once the trial has been adopted into normal practice. The introduction of the
model at around that time may have been a coincident.

This paper is a good example of the strategic thinking required to run successful trials. The authors should be congratulated and encouraged to develop the manual asap.

4. Is the standard of writing acceptable?
Yes.

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