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ESPS Peer-review Report

Name of Journal: World Journal of Methodology

ESPS Manuscript NO: 7350

Title: Choosing Inclusion Criteria that Minimize the Time and Cost of Clinical Trials

Reviewer code: 02511796

Science editor: Gou, Su-Xin

Date sent for review: 2013-11-15 10:50

Date reviewed: 2013-11-24 12:26

CLASSIFICATION	LANGUAGE EVALUATION	RECOMMENDATION	CONCLUSION
<input type="checkbox"/> Grade A (Excellent)	<input type="checkbox"/> Grade A: Priority Publishing	Google Search:	<input type="checkbox"/> Accept
<input checked="" type="checkbox"/> Grade B (Very good)	<input checked="" type="checkbox"/> Grade B: minor language polishing	<input type="checkbox"/> Existed	<input checked="" type="checkbox"/> High priority for publication
<input type="checkbox"/> Grade C (Good)	<input type="checkbox"/> Grade C: a great deal of language polishing	<input type="checkbox"/> No records	<input type="checkbox"/> Rejection
<input type="checkbox"/> Grade D (Fair)	<input type="checkbox"/> Grade D: rejected	<input type="checkbox"/> Existed	<input type="checkbox"/> Minor revision
<input type="checkbox"/> Grade E (Poor)		<input type="checkbox"/> No records	<input type="checkbox"/> Major revision

COMMENTS TO AUTHORS

The topic is novel and one that is much welcomed in this space. The thinking is in the right direction. On this basis we should be happy to support publication. The comments will come from 2 angles clinical (present reviewer) and statistical arguments (alternate reviewer). There are several caveats that could be addressed from a clinical perspective: Title: The title is general and could perhaps be targeted more specifically for genetic mutations in cancer and in this mutation based therapies. The reason is, this area is complex and confounders are at the heart of RCT. It is also too early at this stage to state that the current argument can apply for other diseases whose pathophysiology varies from; acquired non genetic eg infections, or acquired with gene environment interaction eg cardiovascular, metabolic and renal. If the author is keen to persist along this line a strong rebuttal after discussion labelled "limitations" should be added Abstract: Could be improved. It does not state the argument well and is confusing. The key points are highlighted in Introduction paragraph 2 ".....number studied to disapprove null hypothesis increases....novel means of patient selection..."; paragraph 3 "the challenge moving forward....."; paragraph 4 "explain the new paradigm". Include some of these points in the abstract with better and simpler wording. Methods and Results: Statistical reviewer to comment Discussion/Limitations/Conclusion: - Please discuss this argument for genetic polymorphisms. In this case there may be a partial response of varying magnitude. Again I feel the argument is best structured around one line of argument eg breast cancer. Comment in more details on the pathophysiology of this, previous studies on breast cancer and its treatments such as estrogen receptor base therapies etc. Build a coherent argument around one disease and treatment and then discuss how it could be expanded to other diseases with whatever limitations exist. - Should be improved by adding in limitations and a conclusion