Author’s response to reviews

Title: European Medicines Agency Policy 0070: an exploratory review of data utility in Clinical Study Reports for academic research

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Author’s response to reviews:

We thank the reviewers for their approval and we thank the editors for their comments and their positive consideration of our manuscript.

Our response to the editorial comments is as follows:

1. Please be sure to format your manuscript to include each of the following headings/sections, in line with our submission guidelines for research articles. Please also note what should be included in each section:

   - Background:

   The Background section should explain the background to the study, its aims, a summary of the existing literature and why this study was necessary or its contribution to the field.

   - Methods

   The methods section should include:

   The aim, design and setting of the study the characteristics of participants or description of materials a clear description of all processes, interventions and comparisons. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses the type of statistical analysis used, including a power calculation if appropriate.

   - Results

   This should include the findings of the study including, if appropriate, results of statistical analysis which must be included either in the text or as tables and figures.

   - Discussion
This section should discuss the implications of the findings in context of existing research and highlight limitations of the study.

- Conclusions

This should state clearly the main conclusions and provide an explanation of the importance and relevance of the study reported.

Author response: Our manuscript is formatted with the headings in line with the submission guidelines and the content is appropriate for each section.

2. Please format your abstract to include the following subheadings: Background, Methods, Results, Conclusions.

Author response: Our abstract includes all of the listed subheadings as well as an ‘Objectives’ subheading.

3. Please include the Abbreviations section in the main text of your manuscript.

Author response: Abbreviations are now included within the manuscript, after the abstract and prior to the Background section.

4. Please upload English language versions of all questionnaires/ interview guides developed specifically for use in this study as supplementary files. If the questionnaires/ interview guide are not yours or are already published by you, please supply references and/or links to them.

If you upload the questionnaire/interview guide, please provide a section “Additional Files” after References where you list the following information about each of your supplementary files:

- File name (e.g. Additional File 1)

- Title of data

- Brief description of the data

Please ensure that all additional files are explicitly referred to in the main text. Any items which do not meet these requirements may be deleted by our production department.

Author response: Appendix 1 now has a list of the questions asked of corresponding authors at the start, prior to the responses of the authors.

At the end of the manuscript after the references, there is a ‘Additional Files’ heading with details of Appendix 1 (Interview questions and responses).
5. Please clarify whether Ethics approval was obtained, in the Ethics approval and consent to participate section. If you did not need formal ethics approval please confirm that this complies with national guidelines and provide a reference which supports this. Alternatively, supply a statement that says that a local ethics committee ruled that no formal ethics approval was required in this particular case. Please also take a moment to check our website at https://www.editorialmanager.com/bmrm/ for any additional comments that were saved as attachments.

Author response: Ethics approval was not applicable as the main body of the work involved reviewing published work and for the interviews which were conducted, individuals were contacted personally (rather than enrolled into a clinical study). Individuals contacted were under no obligation to reply and those who did provided personal consent for their responses to be shared.

6. As there is a portion of your study that involves human subjects, please clarify whether consent (written or verbal) was obtained from participants, in the Ethics approval and consent to participate section. If consent was not required, please include a statement on whether the need for consent was waived by an IRB or if national guidelines have established that studies such as this doesn’t require consent.

Author response: the following statement is added to the Ethical Approval Section ‘Corresponding authors who responded to interview questions provided written or verbal consent for their responses to be shared within this manuscript.’

A statement regarding the consent of the authors for their responses to be shared is also included within Appendix 1

7. Please remove the response to reviewers documents that are included in the supplementary file, as it is no longer needed at this stage.

Author response: This has been removed

8. Please proofread and ensure that when you upload your revised submission that it is in the final form for publication. Please remove any tracked changes, colored text, or highlighting and include only a single clean copy of the manuscript. Should you wish to respond to these revision requests, please include the information in the designated input box only.

Author response: The manuscript has been proof read and is in the final form for publication

We hope that our manuscript now meets all of the submission guidelines and we look forward to seeing our work published in BMC Medical Research Methodology

Best wishes

Sarah Nevitt