Reviewer’s report

Title: Development of a survey on the regulatory requirements for clinical research in the EU by the European Clinical Research Infrastructures Network (ECRIN) and suggestions for a clinical research classification

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Reviewer: Elina Hemminki

Reviewer’s report:

Referee comments Trials 110609

Referee comments on the paper "Development of a survey on the regulatory requirements for clinical research…"

This paper is part of a survey made by a European group on clinical research. The survey aimed to map the regulation of clinical research in various European countries. To do the survey they defined the different types of research (as different types are regulated differently). The paper describes the process of doing the research classification as well as the resulting groups. The question of clinical research and its regulation is important and the paper is welcome. It could be improved both in terms of clarity and depth.

1a. I had to read the whole paper carefully before the aim and content became clear. Partly this is due to the atypical character of the paper and difficulties to define what are the methods, what results and what discussion. The clarity could be improved by 1) either forgetting the traditional structure and writing by issues, or by 2) focusing on the classification from the beginning to the end, and presenting the development of the questionnaire as part of it.

1b In the restructuring/ focusing you could say early on that this paper will not present the results of regulatory requirements, but they will be presented in other papers (now this information comes late).

2. Particularly the abstract suffers from the problem (comment 1). The aim does not come clear (the aim is better in the main text, p. 8). The last sentence of Methods and Results are ambiguous. Using “we”, “experts” and passive confuses. The conclusion does not come from this study (which was the motive to develop the classification).

3. In the current Methods section, using “we”, “members” and “experts confuses. Is "we" the authors, or all the ECRIN members. Please, systematize and make clear who did what.

4. The meaning of the last sentence of Methods is not clear; expand.

5. Results are very short, and basically just list the categories in a table and text. Furthermore, the problem of “non-interventional trial” is briefly presented. Please, expand Results. The categories and the “includes” column of Table 2 are not
clear-cut, and the readers would benefit of a) examples, b) more discussion of
the nature of each and special difficulties in definitions. Clearly there are several
grey areas, such as “devices combined with medicinal products” (e.g. hormonal
IUDs), “psychotherapy trials without medicinal products” (if drugs are used
similarly in both groups), “psychotherapy vs. psychology studies”, “studies of
nutritional supplements” (vitamins), studies using samples already collected for
other purposes etc. The categories for “Epidemiology” look strange and some
arguments how they ended up with this would be welcome.

6. The discussion of “non intervention trial” is given both in Results and
Discussion. If it was part of the classification process, put all into Results (and
modify accordingly). Otherwise transfer to Discussion.

Details

7. The first sentence of background is not logical (protection and
representativnes are unlikely causes of internationalization of clinical research).
Delete or modify.

8. The fourth sentence of Background gives an important claim (“…differences in
the implementation…” without a reference. Please, add (or give it as your own
unpublished observation).

9. The last sentence of the background mentions “academic research
community”. Please, make clear whether the whole project (ECRIN) is about
academic clinical research or more general including also commercial research.

10. The last para of Results is more of conclusions. Its last sentence is unclear.

11. The end of the 2nd sentence of Discussion is unclear.

12. The end of the 2nd para of Discussion (operationally and semantically) is not
clear. Please, express differently.

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 at the moment