Author’s response to reviews

Title: Scarce quality assurance documentation in major clinical trial registries for approved medicines used in post-marketing clinical trials

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Reviewer’s comment:

As you are aware, the CONSORT guidelines are a minimum set of recommendations for reporting randomised controlled trials (RCT). I appreciate that you are trying to address the reviewer’s comments. However, in this manuscript, you did not undertake a RCT, so following this guidance is not need. My understanding of the reviewer’s comment is that in reference number 16, a point is made, that the authors believe that clinical trial guidelines such as CONSORT, should include statements on the checking and reporting of the quality of drugs and medical products used in clinical research.

I therefore suggest you delete the additional text you put in on lines 112-113 ‘The CONSORT guideline when reporting a randomised trial were followed’, from the methods section as this in inaccurate. I would then add some additional text to the discussion section, about the value/potential impact of including additional statements on the checking and reporting of the quality of drugs and medical products in the Consort statement.
In our previous responses to the reviewer's comments we pointed out that this study was not a clinical trial and therefore the Consort guidelines were not applicable. However, misunderstandings might have occurred in the communication regarding the 1st author’s comment on the Consort guideline which has led to an inappropriate insertion in line 112-113 of the text: “CONSORT guideline when reporting a randomised trial were followed”. This text is deleted in the current version of the manuscript as suggested by the Reviewer. Concurrently, the filed Consort template which was appended to the manuscript as additionnal file was removed.

The authors also agree that inclusion of a statement on ‘the checking and reporting of the quality of drugs and medical products used in clinical research’ is necessary in clinical trial guidelines such as CONSORT. This statement derived from reference paper 16 was assessed by the authors of this manuscript and covered in lines 181-183 which state that: “WHO international standards on CTRs and the ICMJE clinical trial registration policy should be adjusted. However, for an efficient implementation of these guidelines, a concurrent adjustment of WHO and ICH clinical trial regulations is also necessary as previously suggested.[16]"

For more clarity on the need for adjustment of the Consort guidelines, the authors have agreed to specifically refer to the Consort guidelines in line 183 of the new version of the manuscript as follow:

“ … for an efficient implementation of these guidelines, a concurrent adjustment of WHO and ICH clinical trial regulations and the Consort guidelines is also necessary as previously suggested.[16]"