Health Research Authority

Summary of Clinical Trial Results for Laypersons Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use

Consultation Response from the Health Research Authority[1]

v1.0 31/08/2016

Introduction:

1. The Health Research Authority (HRA) was established to promote and protect the interests of patients in health and social care research and to streamline the regulation of such research. We aim, with partners, to make the UK a great place to do health and social care research, to build confidence and participation in health and social care research, and so improve the nation's health. Our responsibilities include the appointment and operation of statutory research ethics committees.

2. Declaration of competing interest: The Health Research Authority has led on the development of these recommendations through an EU-wide taskforce comprised of representatives from industry, patient organisations and academia.

Our Comments

3. This document does not address the provision of lay summaries for children involved in paediatric trials and would benefit from doing so.

4. The MRCT/Harvard guidance which informs much of this document has recently been revised (see MRCT Return of Results Guidance Document (Version 2.1) and MRCT Return of Results Toolkit (Version 2.2)). These new versions will need to be reviewed and incorporated into this guidance. In particular the table provided on page 20 needs to be reviewed to ensure that the language is suitable for lay persons.

5. It would be helpful to provide a glossary for the lay summary pages with a link provided to this from the EU portal/database.

6. The document should include an explicit statement that lay summaries of clinical trial results for laypersons DO NOT require submission to an ethics committee for review.

7. **Line 142**. **Section 6 "Readability and use of plain language":** Whilst a number of readability tools for different languages are already included in this section, it should be expanded as far as is reasonably possible to include readability tools for all the official languages of the European Union.

8. **Line 249. Section 8 "Visuals":** Whilst this section provides a link to "clearly laid out visuals" provided by the U.S. Food and Drug Administration (FDA) it would be helpful to include some examples of relevant visual images within the document itself. Directing readers to the FDA website may inadvertently encourage them to follow FDA guidance more generally when it may be inappropriate/disproportionate to do so.

[1] This response includes comments received by the Welsh Government's Division for Social Care and Health Research.

9. **Page 25. "10. Indication where additional information could be found":** it should add that any links provided to websites for further information should ensure that the landing page on the website is neutral and not promotional.

10. **Annex 1 – Templates:** With regards section 1.1 "Title of the trial" it should state that any short title used in the summary should match the lay title (in local language) given in the EudraCT form.

11. **Annex 1 – Templates:** Many of the examples of "desirable simple, plain language" provided are too complex and not always suitable for a lay audience. However, we are aware that the Harvard guidance which informs much of this document has recently been revised (see MRCT Return of Results Guidance Document (Version 2.1) and MRCT Return of Results Toolkit (Version 2.2)) and these will need to be incorporated into this guidance. The table on page 20 providing examples of "*desirable simple, plain language*" should be reviewed to ensure that the examples are compatible with the revised MRCT guidance and are suitable for lay persons.

12. **Annex 1 – Templates**: In section 5 headed "Investigational medicinal products used" it states that "*If a placebo was used in the trial, this should be stated clearly and the term 'placebo' explained. See the description above in section 3*", however, there does not appear to be any such description in section 3 or elsewhere in the document.

13. **Annex 1 – Templates**: In section "1. Clinical trial identification" it might be helpful to add that whilst "*Other studies may find different results*" systematic reviews may be available that summarise all of the research trials that have been undertaken in this area and, in doing, so provide a much more balanced view than can be provided by looking at just one set of results.

For further information, please contact Clive Collett, HRA Ethics Guidance & Strategy Manager, Health Research Authority (clive.collett@nhs.net).

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