Comment of the Network of Coordinating Centers for Clinical Trials (KKS-Network), Germany

on the

Consultation document "Summary of Clinical Trial Results for Laypersons" (01/06/2016)
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

General remarks:

The recommendations are well written and in itself conclusive.

However, in our view the recommendations focus too much on mathematical/technical tests and concepts on readability. To our opinion and experience, this does not really help in writing a text for lay persons. Readability tests may help in checking a text regarding word count and sentence length and can be used after the summary has been written, but they are of limited value concerning readability (see also comment no. 1) and writing a text for lay persons itself. In addition to this, limitations of such tests become evident when applied to the example sentences provided in annex 1.

In contrast, in our view inclusion of examples (e.g. "good" and "bad" phrasing / visuals) like in the annexes would be more helpful and would make the recommendation more valuable to a person writing a text for lay persons. We would therefore advise to check the weighting of the different chapters and put more emphasis on the general principles and health literacy principles and writing style including examples and less emphasis on chapter 6. This could be complemented with recommendations how to rate the results of the test reader.

Furthermore, a summary of clinical trial results for laypersons should to our opinion not comprise more than 5 – 10 pages, as this would not be easy to understand for the "normal" lay person who has not become a specialist on his own disease.

It is, however, important to take the amount of additional resources (personnel and finances; capacity know-how) the implementation of the recommendations will require into account. This will be a problem especially for academic clinical trials. Summaries for lay persons are needed in the language of each country the trial is conducted in. This might require a master template in English. For all of those different languages, a person with mother tongue would need to prepare the summary, the translation would have to be checked against the template and the translation would need to be checked by patients / patient representatives. The requirement will therefore go along with high additional costs for translations, involvement of patients, resources etc.

Specific comments:

Line 88-89: "*should be aimed at a literacy proficiency level of 2 -3*"
The concept of literacy proficiency levels is not known in all EU countries to an extent that helps writing texts. Without knowledge of the general concept the explanation of proficiency levels provided in the following lines (line 89-103), despite being correct, is not helpful in writing plain language and may be omitted. The description starting at line 104 is more helpful for the objective of the recommendation

Line 127: *"Numeracy principles to describe data and statistics (see section 8 below)"*
Should (probably) read: Numeracy principles to describe data and statistics (see section 7 and 8 below).

Line 128-129: *"Adequate "white space" (for example, separate topics by one or two lines, a minimum of 12-point font)"*
This only makes sense if the summaries are uploaded as e.g. PDF. If summaries are uploaded as plain text, using formatting options of the database, this paragraph could be omitted.

Line 143-145: *"Sponsors should default to a minimum of size 12 sans serif font in the lay summary section. However, an appropriate larger font is recommended where the clinical trial relates to visual impairment or involves older people."*
See comment no. 3 about line 128-129.

Line 143-155: *"Sponsors should default to a minimum of size 12 […] where a larger proportions of adults score at Level 2."*
This is essentially a duplicate of what is said in chapter 5 and can be omitted.

Line 156-160: *"Sponsors are advised to use a language specific reading test to assess the literacy level of each lay summary that they produce. The readability of texts can be formally determined using different metrics. While approaches were initially only developed for the English language, tools are now also available for other languages. The following sections highlight the approaches available for the most commonly spoken languages in Europe."*
To our knowledge, reading tests are not used commonly in languages other than English. In fact, these tests may be misleading and do not focus on the general principles on empathizing with a lay person.

Line 159-231: *"The following sections highlight the approaches available for the most commonly spoken languages in Europe […]"*
The list of available language specific reading test should only be listed as an appendix, since to our opinion, those test will be of only limited benefit while writing a text for lay persons. As stated in line 166-167 "Flesch Reading Ease Test or the Flesch-Kincaid Grade Level Test based on counting syllables and sentence length." and line 171-172 "The Flesch-Kincaid Grade Level Test uses an algorithm that includes both the number of syllables per word, as well as average sentence length […]" these tests focus on counting words, sentence length and syllables and not on content and readability. The example

recommendation of line 108-109 to use "high blood pressure" rather than "hypertension" is correct concerning readability, but results in using three versus one word, which would result in a lower readability using readability tests. In general, replacing technical wording with common wording often results in higher word counts.

Line 233-241: *"Other considerations [...]"*
This paragraph should get a much higher weight within the recommendations, since this may really help in writing a text for lay persons. This could be complemented with recommendations how to rate the results of the test reader. For example, the raters who represent the target population get a standardized questionnaire after reading the report, to assess the readability.

Line 249-262: *"8. Visuals"*
Inclusion of examples (e.g. "good" and "bad" visuals) might be helpful.

Annex 1 - Templates
The template and example sentences are helpful.
We applied the Flesch-Kincaid Reading Ease Test on the example sentences given in annex 1, and evaluated, whether a score of 70 and above ("easy to read") was reached. We got the following result: min 47.5, max 82.7, mean 66.5. The example sentences, while easy to read, thereby not always score as "easy to read", which also shows the limited value of such tests.

Annex 2 - Neutral language guidance in describing results
The list provided is very helpful and easy to transfer into the writing process.

Köln, Berlin, 31.08.2016