European Commission (EC) Summary of Clinical Trial Results for Laypersons			
Page Number	**Text Line**	**Reference** *(if applicable)*	**Comments**
Section 5 'Health Literacy Principles and Writing Style', page 4 and Section 6 'Readability and use of plain language', page 5	Text lines 88-94; 97-103 and Text lines 148-155; 164-175	1. Kathy Everts Danielson. (1987). Readability Formulas: A Necessary Evil? *Reading Horizons*. Volume 27, Issue 3 (4), 178-188. Hyperlink to article	The International Adult Literacy Survey (IALS) Levels (specifically Level 2-3) referenced to determine adult literacy in the consultation paper and the varied readability tools (e.g., the Flesch Reading East Test) that are recommended to assess readability are difficult to apply in all geographic areas. The guidance suggests that "*text for the public should be aimed at a literacy proficiency level of 2-3*" per IALS and "*research across Europe*" [Line 88-89]. • IALS Level of 3 is described [line 100-102] and a corresponding grade level is provided: "*roughly with high school completion levels*" [line 102-103]. • IALS Level of 2 is described [line 98-100], but a corresponding grade level is not provided. It is difficult to quantify what "*high school completion*" means for literacy in areas like the United States (where you have programs like college preparatory public high schools vs. rural public schools), across the EU, and elsewhere. Literacy levels at different high schools are highly variable. • However, it is suggested that, for English language texts, a Flesch Reading Ease Score of "*70 and above is easy to read*" [line 170] and "*An ideal reading grade level is 6th grade which is close to the literacy level of the general population*" [line 173-174]. Literacy at high school completion levels is enormously variable. As such, the use of the IALS Level 2-3 grade level, corresponding to a "*high school completion*" literacy level, is not a useful metric. The majority of readability experts advise against writing plain language documents at a Grade 12 of high school graduate reading level.

© Association of Clinical Research Professionals | acrpnet.org

			Variations in the application of language-specific readability testing are also seen from region to region, therapeutic area to therapeutic area, and from institution to institution. The consultation paper does not specify that a template produced in English, written according to the parameters required by Annex V, completed according to a 6th grade readability level (as verified by the appropriate test, for the country of origin) could be translated for end country review without the need for additional, duplicative, readability verification methods during end-country review. This may be an important process clarification, as sponsors (either directly or via translation company vendors) have an obligation to stay on tone and level of literacy, and to ensure the representation of the meaning/ideas of the original document (including the level of terminology). A discussion of expections for translation that incorporates quality and in-country review by native language speakers would alleviate sponsors of additional administrative burdens for duplicative multi-country language testing, The consultation paper suggests "*Sponsors are advised to use a language specific reading test to assess the literacy level of each lay summary that they produce*" [line 156-160]. With regard to drafting in English, testing the readability of writing in English by using the Flesch readability tests, then translating into other languages, "*This can be helpful in multi-country studies where summaries are first drafted in English and then translated into other languages*." [line 167-168] Publications on readability verification methods clearly illustrate that there are dangers to using these formulas as the exclusive basis for anticipating document literacy levels.[1] Brief sentences and easier words may make a document easier to read, but may dilute trial summaries past the point of being impactful, and may alter comprehension of important study information that needs to be conveyed to the public. Translators have an obligation to maintain the tone, level of literacy, and the original meaning/representations expressed within the original, template summary document.
Section 5 'Health Literacy Principles and Writing Style', page 4	Text line 126		• Bullet points should be employed, instead of paragraphs, to improve comprehension. More explicit guidance should be given in regards to the use of bullet points to promote clarity; • Bullet points are generally recommended for unordered lists, also known as groups of similar items; • Text describing sequential actions is better presented in paragraphs; and • Text describing steps in order should be numbered. Bulleted lists should be 4 to 7 items maximum and should not be overused.

Section 7 'Numeracy', page 7	Text lines 243-247		We also urge that you recommend in this guidance that clinical trial teams should consider calculating or converting numbers. Readers are unlikely to conduct even basic math. Instead of "Lose 5% of your body weight," do the math for the reader, or show a few examples. It would also be helpful to consider the option for posting lay summaries with hyperlinks to more detailed charts that show specific tables with specific values, if applicable. Provide estimates for longer time periods. Cumulative or long-term risks often require readers to extrapolate information from one time period to another. For example, if a patient knows the annual risk of taking a medicine, but intends to take it for many years, they must understand how the risk might change over a longer period of time. Do the math to help readers understand risk over time. Attempts should be made to avoid influencing the reader in any way possible, when creating lay language summaries, including the use of any graphical elements that do not provide clarity and may influence reader sentiment.
References - Annex I - Section 6. 'Description of adverse reactions and their frequency', page 17			"Sponsors should note that the lay summary calls for a description of adverse reactions whereas the technical summary refers to adverse events. This difference is intentional and means that text should not be simply copied across from one section to another." We applaud the distinction between adverse reactions and adverse events. At this time, many sponsors have been copying adverse events from the full technical summary in the Clinical Study Report (CSR) into the lay summary, without taking the additional step to parse out adverse reactions (an experience that has an association with use of the test article). In earlier phases of study with smaller participant populations or in rare disease communities, this has the potential for alarming the public and inflating their perceptions of danger for use in seeing all adverse event information. This potential bias in public perception regarding the potential safety of investigational medicines will be clarified through the transition of posting adverse reactions versus aggregate adverse event information, and is supported by ACRP.