Collyar comments to EU on public summaries

To the European Commission Unit B4 "Medical products – Quality, Safety and Innovation,"

My name is Deborah Collyar, Deborah@tumortime.com, and I am responding as an individual.

Thank you for allowing public comments on the draft consultation document for "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."

While I am submitting these comments as an individual, I've led many efforts in plain language results for decades, with more personal hands-on experience than anyone else to which I am aware. This started with my non-profit, the Clinical Trials Information Project (CTIP), that became a catalyst for U.S. National Cancer Institute improvements (Physician Data Query (PDQ), cancer.gov, and eventually clinicaltrials.gov). As co-chair of the Cancer and Leukemia Group B Committee on Advocacy, Research Communication, Ethics, and Disparities (and now Vice Chair of the Alliance for Clinical Trials in Oncology Publications Committee), I created a process that has produced over 40 public study result summaries. I am also co-chair of the MRCT Center of Brigham and Women's and Harvard Return of Results Working Group (which the consultation document references), and am directing Health Literacy Missouri's (HLM) new Plain Language Research Summary service. I have also created many patient advocate opportunities to work directly with, rather than just supporting, researchers and started Patient Advocates In Research (PAIR) to continue these efforts globally.

Overall, the consultation document contains useful information that should help produce research summaries for patients, their families, and the public. This is a critical step to ensure clear, quality information that provides much needed transparency, and I commend your efforts and leadership in this area. One can only hope that other countries' governmental agencies will soon follow your lead by creating compatible requirements of their own. Below, I list suggestions for additional clarity, important word changes that address unintended barriers, and a few errors.

First, the extensive use of the terms "lay," "laypersons," "lay summaries," "lay language," "lay title," and "lay audience" run counter to the goal of producing clear, understandable summaries for trial participants and the public at large. "Lay" is often used to reinforce the superiority of an elitist group (i.e. "professionals") to separate themselves from an audience they prefer to avoid. The constant use of these terms in the consultant document (and corresponding EMA No 536/2104) sets up an artificial barrier and mindset that creates separate classes where none should exist. Please use more accurate terms, such as "general summary," "simple language," "patients," "people," "persons," and "the public." Specific lines that need to be changed include: 7, 47, 49, 50, 51, 57, 58, 60, 66, 143, 148, 157, 241, 272, 273, 288, 289, and many throughout Annex 1 and the rest of the document.

Another term that should be eliminated (for similar reasons listed above) is "subject," which is also referred to in Annex V requirement 4 of the EMA No 536/2014. Human beings should not be called "subjects" simply because professionals cannot think of a better term than they use for lab rats. The term "subject" is a verb to patients, not a noun. Please replace it with "participant" or "patient" instead, especially since these words are used throughout the rest of the consultation document.

There is confusion, and possibly conflicting information, between statements made within the consultation document that need to be clarified:
Lines 73/74 say "Develop the layout and content for each section in terms of style, language and literacy level to meet the needs of the general public."

Collyar comments to EU on public summaries

Lines 95/96 say "Communications written for the public should use simple everyday language to ensure ease of reading and understanding."
These statements are incredibly important, and I wholeheartedly support them.
Unfortunately, the statement in Annex 1, page 13 states "It should be noted that the wording of the ten elements cannot be changed but that sponsors can, if they wish, combine categories where this makes sense," and that the order can be changed. The words used as headings from Annex V's 10 requirements do not meet health literacy standards and would be very confusing for patients and the public. It is imperative that sponsors are able to change the words of the requirements if they are used as headings on plain language research result summaries. This applies especially to pp. 13-25 that list Annex V requirements 1, 3, 4, 5, 6, 7, 8, 9, and 10. The MRCT template offers good alterative words, and I would be happy to help as you resolve this situation.

There were references to language levels 2-3 in Europe (lines 148-155) and 6th grade level in the US through Microsoft Word (lines 165-175) that do not seem compatible. It was mentioned that Level 2 is approximately high school level, which matches grades 9-12 in the US. There may be additional discrepancies listed in other languages as well (lines 176-231). Please clarify the language levels so they consistently address the same target between various language tools.

All references to the MRCT Guidance Document and Toolkit should include the latest revisions. This includes lines 246-247, 284-287, p. 11, pp. 24-25, and p. 28. The latest versions are posted at http://mrctcenter.org/projects/return-of-results-to-participants/.

It was mentioned in Annex 1 p. 18 that the term "side effects" could be used instead of "adverse reactions," but the Annex V heading requirement 6 uses "adverse reactions." Please clarify that it is acceptable to change the heading names to fit clear, plain language health literacy standards.

Pp. 18 -19 also states that side effects for each group/arm should be listed separately, but if the side effects are the same for each group/arm, this can become confusing and lengthy. For these cases, please allow sponsors to list side effects once and then show the amount of side effects for each group/arm.

There is potential confusion with the way endpoints are described on p.19, Annex 1. Please clarify the kind of endpoints that would fit the statement, "Patient relevant secondary endpoints and results by study arm." For instance, sponsors should list primary endpoints, and secondary endpoints that are clearly measured regarding safety and clinically actionable results.

The template in Annex 1 has inconsistent grammar and health literacy principles in the suggested wording. Please use action verbs consistently with bullets. Simpler words can also be used throughout the template.

On p. 19, the heading should not have an "s" on "Overall Results of the Clinical Trials."

Finally, demands that force conformity to the literal interpretation of the law (rather than its intent) is counterproductive when creating useful information for patients, their families, and the public. Please be prepared to quickly address the issues that will surface from this regulation. In addition, regulations and corresponding documents need to change often and openly, and encourage innovations that will develop over time. For instance, while the current instructions are firmly focused on print formats, it is clear that other issues will surface when more innovative web applications are produced. Thank you again for seeking public comments to your documents.

Collyar comments to EU on public summaries

I consent to the publication of all information in my contribution in whole or in part including my name/the name of my organisation, and I declare that nothing within my response is unlawful or would infringe the rights of any third party in a manner that would prevent publication.