26 August 2016

Submission of comments on Consultation Document '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 of medicinal products for human use.'

Comments from:

EUCROF
European CRO Federation
New office address:
Kuipersweg 2T
3449 JA WOERDEN
The Netherlands
Email: info@eucrof.eu
Internet: www.eucrof.eu

Representatives on this matter:
Simon Lee
Member of the EUCROF Clinical Trials Legislation Working Group
Tel.: +44 (0)115 931 5560 | Mobile: +44 (0)7810 890 657
Email: Simon.Lee@quotientclinical.com

Dr Dagmar Chase
Vice-President EUCROF
Chair of the EUCROF Clinical Trials Legislation Working Group
Tel.: +49 (0) 89 92 92 87 0 | Mobile: +49 (0) 172 85 36 338
Email: dagmar.chase@clinrex.com

Submitted to: SANTE-B4-GL-results-laypersons@ec.europa.eu

EUCROF
European CRO Federation

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	Comment: We welcome the opportunity to provide comments on the Consultation Document Summary of Clinical Trial Results for Laypersons. The provision of Templates in Annex 1 and suggested wording is particularly helpful. For the Summary of Clinical Trial Results for Laypersons we agree that "readability testing" or "user testing" should, **where feasible**, be carried out on a small number of people who represent the target population. However, for Phase 1 clinical studies, which are conducted in healthy subjects, "readability testing" or "user testing" should also be able to be carried out using members of the public.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome
48		Comment "… summaries will be made available in the EU Portal and Database." The publication of the information will be made public through the EU Database. Proposed Change: "… summaries will be made available in the EU Database."	
57		Comment "… clinical trial results for laypersons by sponsors and investigators." It is a clear sponsor responsibility (see section 3. of the document) to publish the summaries of results. Proposed Change: "… clinical trial results for laypersons by sponsors."	
61 - 63		Comment "Given this wide audience, the summaries will need to **be** take into account the average literacy level of the general population, provide simple explanations and apply other measures to support health literacy."	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome
		Examples for measures to implement should be given Proposed Change: "Given this wide audience, the summaries will need to take into account the average literacy level of the general population, provide simple explanations and apply other measures to support health literacy, e.g., the use of visuals, the use of "white space" between different topics, etc. ."	
76 – 78 vs 146-147 (Readability and use of plain language)		Comment There is repetition in the following sections: **General Principles:** - Focus on unambiguous, factual information. - Ensure that no promotional content is included (See neutral language guidance in Annex 2). **Readability and use of plain language** Keep the summary factual to avoid any promotional language (See neutral language guidance in Annex 2).	
79 - 80		Comment "Follow health literacy and numeracy principles (see section 6 'Health Literacy Principles and Writing Style" Wrong reference – should be section 5 In addition, Numeracy principles should be added. Proposed Change: "Follow health literacy and numeracy	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome
		principles (see section 5 'Health Literacy Principles and Writing Style' and section 7 'Numeracy')"	
81 - 83		Comment "Consider involving patients, patient representatives, or advocates in the development and review of the summary information to ensure that it truly meets their needs." This won't be feasible for some studies, but where it is a possibility, it may enhance the final version. Proposed Change: Consider involving patients, patient representatives, advocates or members of the public in the development and review of the summary information.	
127		Comment "Numeracy principles to describe data and statistics (see section 8 below)" Wrong Reference, numeracy principles are described in section 7 Proposed Change: "Numeracy principles to describe data and statistics (see section 7 below)"	
237 - 238		Comment "Depending on the nature of the study, this could be patients with a particular disease or it could be members of the public." Patient representatives, e.g., members of a patient organisation or care takers, should be added here as well. For	

Deleted: or

Deleted: to ensure that it truly meets their needs. This won't be feasible for some studies, but where it is a possibility, it may enhance the final version.

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome
		example, in case the disease disables the patients to read (e.g., Alzheimer's disease), a representative would be a good test individual. Proposed Change: "Depending on the nature of the study, this could be patients with a particular disease, patient representatives or it could be members of the public."	
240		Comment "… than patients." The better word would be "subjects" when talking of vaccines. Proposed Change: "… than subjects."	
271-276		Comment We recognise the importance of acknowledging the contribution of study participants and expressing thanks for their time. However, in our view this paragraph is outside of the scope of Annex V of the Regulation and should be removed.	
Annex 1 Section 4.1 and 4.2		Comments 1. First bullet point in 4.1 should be "Total number of subjects"	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome
		2. As the number of subjects in a Phase I clinical study is typically very small it would be preferable to provide a broader rather than a specific breakdown of participants by age and gender as follows: "The study included male and female healthy subjects aged 18 to 65 years."	
Annex 1 Section 9		Comment The nature of drug development is such that providing accurate timelines for further related clinical trials is not easy and depends on many factors. We suggest this section provides a choice of possible statements as follows: • Clinical trials with Drug X are ongoing and further trials are planned. • Further clinical trials with Drug X are planned. • No further clinical trials with Drug X are planned at the current time.	