SUMMARY OF THE RESPONSES TO THE PUBLIC CONSULTATION ON "SUMMARIES 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

1. GENERAL REMARKS

Article 37 of the Clinical trial Regulation (EU) No 536/2014 requires that sponsors provide a summary of clinical trial results in the EU Portal and Database, in a format understandable to laypersons. The main objective of this document is to provide recommendations and templates for the production of a summary of clinical trial results for laypersons by sponsors and investigators, in accordance with Annex V of the EU Clinical Trials Regulation.

With this public consultation the Directorate General for Health and Food Safety, DG SANTE, intended to seek the views of stakeholders – and other interested parties – on the *Summaries of Clinical Trial Results for Laypersons*, which has been developed by the expert group on clinical trials in preparation for the implementation for the Clinical Trials Regulation (EU) No 536/2014.

This document presents a factual summary of the responses to the public consultation. It does not present the views of the European Commission.

2. CONTRIBUTORS TO THE PUBLIC CONSULTATION

The number of contributions received was 46. Eight contributors claimed confidentiality or anonymity over their submissions. Their contributions will therefore not be published or published only in anonymous form.

3. OUTCOME OF THE PUBLIC CONSULTATION

In summary the contributors commented on the following aspects:

General aspects:

- Terminology to clarify meaning or provide plain language versions
- Acknowledge that writing complex concepts in plain language may add considerable length which in and of itself may decrease comprehension so content has to be carefully considered.
- Remove areas of duplication

Health Literacy principles and writing style:

- Add the statement that the most readable colour combination is black text on a white background and that sponsors should avoid using white text in on a coloured background as this can be harder to read.
- Describe when use of medical terminology might be helpful or appropriate

Readability and use of plain language:

- Explain that whilst sponsors are encouraged to use a language specific reading test, this alone does make the text meaningful or readily understandable and as such should be used in combination with health literacy guidance.
- Recommend the use of paediatric focused lay summaries where appropriate.

Visuals:

- Remove reference to creative use of videos.

Template:

- Replace original ten headings as specified in Annex V with plain language, user friendly versions.
- Include an abstract in the main template as a non-mandatory suggestion
- Allow sponsors to specify longer term follow up for some trials where appropriate
- Remove requirement to refer to all brand/trade names used in the countries where the trial took place and instead should include the name of the trial medicine (and comparator(s)) as used in the protocol and trial registration.
- Clarify the requirements for reporting adverse reactions including using a clearly communicated 'cut-off' where needed.
- The requirement to report of outcomes should be limited to primary endpoints and additional safety data of importance to the overall results trial. Readers wishing to see secondary endpoints should be directed to the technical summary.
- Terminology in the table of commonly used endpoints was amended.