14 September 2020

Submission of comments on 'Good Lay Summary Practice'

This public consultation will welcome comments between 26 June and 14 September 2020.

Please provide your general comments in the first part of this form and your detailed comments in the second section. Please give each comment a consecutive number starting with 1. Please do not comment on spelling and grammar.

Please submit your completed form electronically in WORD format to the following address:

GLSP@efgcp.eu

Comments from:

Name of organisation or individual
German Association of Applied Human Pharmacology (AGAH e.V.), Hamburg, Germany info@agah.eu

1. General comments

Comment number	General comment (if any)
1	AGAH suggests a specific Lay Title identifies every clinical trial from the planning onwards.
2	AGAH suggests that Lay Summaries (LS) should be short to enable quick information about the topic of the trial. An abstract may increase the readability of the LS of a more complex clinical trial.
3	AGAH would like to question the effectiveness of involvement of patients / patient organisations in the planning and reporting of early phase trials without therapeutic intent. AGAH suggests to exclude Phase I trials from this form of patient involvement and to be coherent regarding patient involvement in later phase trials.
4	AGAH feels that the GLSP is a very complex document. Especially for academic trials, the involvement of lay persons in all parts of the trial planning and reporting processes may be overwhelming and prove unfeasible.
5	AGAH suggests that transparency is required regarding potential conflict of interests of patients / patient organisation involved in the trial planning and reporting process.
6	AGAH would like to point out that participants in early phase trials without therapeutic intent are recruited for a specific trial. After completion of such a trial, there is no further relationship between an investigator and the trial participants. Thus, dissemination of LS via the investigator - at a time point of up to 30 months after end of the trial - seems not feasible for early phase clinical trials.
7	AGAH suggests that regulatory bodies and ethics committees demand improved lay person readability for patient information sheets and informed consent forms.

Please add more rows if needed.

2. Specific comments on text

Comment number	Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
1	135	Comment: Individual patients who receive or seek treatment Proposed change (if any): AGAH does not see Lay Summaries (LS) fit to provide recommendations for individual treatment. On the contrary, LS should clearly state that they report the results of only 1 trial and other trials on the same topic may provide other conclusions.
2	243-245	Comment: Trial team members ... 'can confirm' that the LS represents the results accurately. Proposed change (if any): 'The sponsor must ensure that the LS represents the trial results accurately.'
3	326	Comment: How long is a patient a 'lay person' ? After how many trials is this person rather an expert and can no longer add a different perspective? Please consider also that in early phase trials without therapeutic intent the involvement of 'one or several patients in the process of LS planning, development, translation and dissemination' may neither be required nor prove feasible (very tight time schedules). Proposed change (if any): Suggest to add 'excluding early phase trials without therapeutic intent'. 'If sponsors of later phase clinical trials decide against patient involvement, they should provide a rationale.'
4	331-354	Comment: Paragraph is too long for body of report. Process is believed to be very complex and only feasible for commercial sponsors but not for academic sponsors. Proposed change (if any): AGAH suggests shortening this paragraph and transfering text to the appendix.

Comment number	Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
5	423-428	Comment: formatting is incorrect Proposed change (if any): Change to grouped style / justification
6	618	Comment: 'key' entry criteria Proposed change (if any): repeat 'key' to clarify that not all entry criteria need to be stated
7	628-631	Comment: Paragraph on safety and reporting of adverse reactions is too short. AGAH feels it is very uncommon and will create large discrepancies versus the technical / scientific clinical trial report synopsis if the LS reports serious and non-serious adverse reactions separately. Proposed change (if any): Please enlarge on this very important issue and move text from Appendix to Body. The total number of adverse reactions and the subgroup of serious adverse reactions should be given as is the case in the scientific synopsis. Numbers stated should not differ between these documents. The frequency of adverse reactions should be denoted with 'frequent', 'infrequent', 'rare', matching the terms generally used in package inserts / SmPCs.
8	672	Comment: Table numbers do not differentiate between Body and Appendix Proposed change (if any): Please use unambiguous table numbering

Comment number	Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
9	672	Comment: Title of Table 3.1 is hard to understand Proposed change (if any): AGAH suggests to clarify that this table addresses sponsors writing LS
10	684 - 689	Comment: term 'source documents' is defined here, yet used already in line 249. Proposed change (if any): Please link line 249 to lines 684- 689 regarding 'source documents'
10 a	249	Comment: term 'source data' is misleading. In this context 'source data' does not denote the 'source data' established by an investigator in a clinical trial, yet means 'source documents'. 'Source data' is a specific 'terminus technicus'. Proposed change (if any): Please change to 'source documents' and link to the respective definition in lines 684-689
11	760	Comment: Paragraph on Quality Controls of LS is very short Proposed change (if any): AGAH suggest to enlarge on the topic of Quality Controls of LS
12	977	Comment: 'use the document' Proposed change (if any): Please add use 'of' the document
13	1103 ff	Comment: Translation is a very complex and costly process Proposed change (if any): AGAH suggests to enable public funding for multi-national, academic trials requiring translation of LS

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14	1249	Comment: AGAH feels this statements rises many issues concerning how to document the respective question to the trial participant, how to document the wish of the trial participant and how to document the dissemination to the trial participant. Has the Ethics Committee to be involved in this process? Proposed change (if any): AGAH suggests deleting this line as it rises further issues without answering them.
15	1354 - 1439	Comment: AGAH questions the described process of investigator dissemination of the LS. For early phase clinical trials without therapeutic intent the described process is not feasible. There is no relationship between investigator and trial participant other than the trial-specific contact. Ethics committees consent would be required to contact trial participants after end of the trial. The entire LS dissemination process via the investigator would have to be reflected in the informed consent and add several steps to documentation and quality control (how was consent obtained and documented to receive LS, when was LS disseminated, how was receipt of LS verified, etc.). Proposed change (if any): AGAH suggests adding also restrictions, disadvantages, and quality assurance issues associated with the dissemination process of LS via the investigator.
16	1441-1450	Comment: formatting is incorrect Proposed change (if any): Change to grouped style / justification
17	1627	Comment: Typo ... the average proficiency level is ‘2 -32 2 ‘. Proposed change (if any): Please correct typo regarding proficiency level 2-3

Comment number	Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
18	1982-1984	Comment: see above table numbering, '***' not defined Proposed change (if any): Please use unambiguous table numbering, please define '***', second column to be formatted left-bound?
19	2062	Comment: see above Proposed change (if any): The frequency of adverse reactions should be denoted with 'frequent', 'infrequent', 'rare', matching the terms generally used in package inserts / SmPCs.

Please add more rows if needed.