Comments for EC Public Consultation on recommendations for Summary of Clinical Trial Results for Laypersons

Name of Organisation: Gilead Sciences International Ltd.
Category of Organisation: Company/Business

Line no.	Comments
81-82	*"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 is not feasible for every study and every Laypersons Summary. By the time the Laypersons Summary is written and submitted, the trial has been closed for a significant period of time. Going back to patients and/or investigators at that point is not practical. Given the wording of the statement we assume this is optional and not mandatory.
130-132	*"Links to additional information, and resources for online summaries and background information. Such links need to be minimal since hyperlinks may become out of date over time."* This is contradictory to Section 10 of provided sample template: "Indication where additional information could be found" Clarification is needed.
142-241	*Section 6* The section contains a lot of detail regarding the methodologies and in some cases the history of their development. If the intention is to standardize the use of these methodologies, it would be simpler and more helpful to indicate which should be followed for each language and provide a relevant literature reference, much like Section 7 is structured.
156-157	*"Sponsors are advised to use a language specific reading test to assess the literacy level of each lay summary that they produce."* Will this be a requirement for submission of the Laypersons Summary for each study? If Yes, this could be a significant cost and resource burden to the Sponsor.
192-198	This paragraph does not add any useful information. Better to concentrate on the suggested methodology rather than explain the history of how it was achieved.

199-202	As above. Suggest beginning the Italian section at “The GULPEASE formula…” on line 202.
215-224	As with the Italian section, it would be more helpful to simply state which methodology should be followed.
260	*"Creative solutions to ensure understanding could include videos, cartoons and animation."* Embedding videos and/or animations could significantly increase the size of an individual Layperson Summary file submitted. Is there a file size limit for the Laypersons Summaries? Is there a size limit for Laypersons Summaries at the Study level? (i.e. studies involving multiple EU member countries will result in a significantly larger Laypersons Summary Package). If Videos and/or animations are included in the Laypersons Summary, are there format requirements? (e.g. Videos: AVI, MOV, MPG, MP4, etc.). Same question for animations (e.g. GIF, DHTML, Flash, Silverlight, etc.).
265-266	*"As a minimum, the summary is expected to be provided in the local language of each of the EU countries where the trial took place."* Do Laypersons Summaries need to be validated (i.e. back translated) & tested for readability? Providing Laypersons Summaries "in the local language of each EU countries where the trial took place" will result in significant cost and effort by the Sponsor. Is the requirement to produce Laypersons Summaries in the "Local Language" or Official Language of the EU countries where the trial is conducted? e.g. The Official language of Spain is Spanish. However, local dialects (depending on location of Sites / Patients) may be spoken such as Galician, Catalan, and Basque. For countries with multiple Official Languages (e.g. Belgium (Flemish, French, German), will the requirement be to produce Laypersons Summaries for each Official Language?
Annex 1 - Templates Section 1	Are Phase 1 studies in scope for Lay Summaries? Phase 1 studies are PK, scientific, complicated to interpret, and not conducted in patients but in healthy volunteers. The general population would be interested in the studies and results related to the actual population of interest. Many of these studies really do not provide much information in that regard. Suggest that layperson summaries be required only for studies

	of subjects with a target condition and exclude Phase 1 studies from the requirements.
Annex 1 - Templates Section 1.1	Is it the expectation that the lay title provided in the lay summary be identical to the lay title that was included in the EudraCT forms at the time of CTA submission?
Annex 1 - Templates Section 3.2	What level of specificity regarding dates is required? From the example provided it seems that Month & Year is specific enough, without proving actual dates. Clarification is needed if this is not the case.
Annex 1 - Templates Section 3.3	Same comment as above. Why are Phase 1 studies in scope for Lay Summaries? Would this need to be done for each Phase 1 study or is this more of an overall lay summary of the various Phase 1 trials? Phase 1 studies generally would not provide information of interest to the general public.
Annex 1 - Templates Section 4.2	Are figures such as the example provided a requirement or optional? The implications for Biometrics team could potentially be quite significant if these types of additional tables/figures, etc. need to be produced.
Annex 1 - Templates Section 5	*"….should use the generic name only to avoid long lists of names."* This may not be practical in the case of comparator products that have multiple generic components.
Annex 1 - Templates Section 5	*"For early phase trials..."* Same comment as above regarding if Phase 1 trials should be in scope for Laypersons Summaries. Suggest that Phase 1 studies should be out of scope.
Annex 1 - Templates Section 6	*"Providing very long lists of adverse reactions in technical language is not helpful.Consider using a simple term, such as "side effects related to the treatment" to refer to adverse reactions."* Unsure that this analysis for ADRs is conducted or applicable to all studies. Phase 1 studies are often completed before ADR lists are identified. Therefore, there wouldn't be a reliable way of knowing the set of "side effects related to the treatment". For this reason, what is presented are only the most common ADRs.
Annex 1 - Templates Section	*"Findings from this study will be used...to combine with other treatments in [patients with condition/disease]"*

8	Unclear wording as it implies that *findings* from the study will be combined with *other treatments.* Suggest to reword to state that that findings from this study may be used to help design studies of the product in combination with other treatments.
Annex 1 - Templates Section 8	*"Were there any differences in side effects?* • *Sex: Treatment A had a similar side effect profile in men and women.* • *Ethnic groups: The number of patients from ethnic minority groups was limited. This means that it was not possible to make any conclusions regarding differences in side effects among ethnic groups.* • *Age: All patients who took Treatment A had a similar side effects no matter how old they were."* "Gender" may be more appropriate than "Sex" for Laypersons Summaries. Race is more appropriate than ethnicity. Suggest not to state "All patients" on "Age" point as there may be differences in individuals that are not apparent in the integrated data. Why not worded similar to the previous points e.g. Treatment A had similar side effect profile across age groups. This can be defined if specific cutoffs were used (eg, >65 vs <65).
Annex 1 - Templates Section 9	Is this section mandatory or optional? This seems very speculative and difficult for the Sponsor to complete, also because competitors would be most interested in this information. Suggest this section is optional given that trial plans often change very significantly.
Annex 1 - Templates Section 10	Assuming the Sponsor will not be able to update or modify the record once it is published and available to the public and even if Sponsor is able to update record, it is highly unlikely that any Sponsor would spend the time and effort to update additional information. This could potentially allow for scrutiny / criticism of Sponsor if additional information becomes available after the laypersons Summary is published. Also the Sponsor is not able to manage the content of related webpages, which may be sponsored (ie, links with advertisements) and content may change over time.