Discussion and agreement on critical aspects of GLSP, TC 18 November 2020
DG Santé, GLSP Initiative

# Minutes

Participants: [redacted]

Aim of the telephone conference was further clarification of elements in the GLSP Recommendations that will be presented and discussed during the CTEG Meeting on 20 November 2020.

**Lay summaries for interim results**

Proposed approach to Interim result reporting in CTIS:

- A planned interim analysis of the primary endpoint is specified in the study protocol. If it is intended to make the results of this interim analysis public in CTIS then this needs to be described in the protocol as well.
- With respect to the mandatory reporting timelines, the "Technical" Summary of the interim analysis results needs to be prepared as specified in the EU CTR in Annex IV, and the Lay Summary as specified in EU CTR on Annex V, if the interim analysis results in CTIS are supposed to be made publicly available.
- The "Technical" Summary and the Lay Summary of the interim analysis results should be published in CTIS only if the interim result summary is published. However, currently CTIS does not foresee an upload of a LS on interim analysis results. The Lay Summary needs to clearly state that they summarize interim results and the reporting process mentioned in protocol and PIS/IC.
- Once the final analysis is available a final "Technical" Summary and a final Lay Summary will be provided and both the "Technical" Summary and the Lay Summary for the interim results will be replaced in CTIS by the documents describing the final analysis results. The Lay Summary will state clearly that these final results supersede the presentation of the interim analysis results. This reporting process needs to be presented in the protocol and PIS/IC.

If CTEG would endorse the provision of an option to upload also interim analysis results Lay Summaries, EMA would be approached to explore the feasibility of such an addition at this stage of CTIS development.

**Dissemination of Lay Summaries**

- The GLSP should specify that it is a legal requirement to upload Lay Summaries to CTIS within the specified time frames. Sponsors may wish to enable additional direct and/or indirect dissemination. Direct dissemination may be relevant to inform patients who have no access to CTIS but this cannot replace the legally required CTIS publication of the Lay Summary.
- The GLSP should specify clearly that such additional direct and/or indirect dissemination would only be best practice under the following conditions:
    - Sponsors should have a clear policy to provide Lay Summaries for all trials within the scope of the CTD/CTR, regardless of outcome
    - The plan to directly and/or indirectly disseminate a Lay Summary beyond CTIS should be specified in the study protocol and should also be explained in the PIS/IC.

- Sponsors' policy should state that all efforts will be made to ensure non-promotional content, appearance and website-context of Lay Summaries.
- The plans for upload of results in CTIS and additional dissemination pathways need to be mentioned in study protocol and PIS/IC, subject to review and approval in the CTA process.

**Inclusion of secondary endpoints in Lay Summaries**

- CTEG will decide to either follow
  **A)** the "Recommendations of the expert group" i.e. limit the presentation of results to the primary endpoint
  **or B)** will adopt the position of the EC Q&A document that the primary endpoint and patient-relevant secondary endpoints should be reported.
- Should option B be selected, CTEG will review the draft recommendation that an endpoint can be considered patient-relevant and thus be presented in the LS if:
  - This secondary endpoint is pre-specified in the study protocol and the statistical analysis plan
  - It is selected based on input from patients wherever possible
  - Is evaluated statistically (with sound consideration of issues pertaining to multiple testing)
  - Concerns an aspect of treatment that is of particular relevance to patients

**Encouragement to apply GLSP to other than clinical studies**

- To be deleted

**Definition of "End-of-Study"**

- Should not specify LPLV but refer to End-of-Study as defined in Art 2.2.26 of the CTR

**Reference document for LS quality control**

There is still a need to define Clinical Study Report and its relevance as the basis for the Technical Summary and the LS:

Post meeting note: Art. 37.4 CTR mentions that the Clinical Study Report needs to be uploaded by the marketing authorization holder in CTIS 30 days after the marketing authorization has been granted. The List of Content of the CSR is defined in "Note for Guidance on Structure and Content of Clinical Study Reports (CPMP/ICH/137/95)". Thus, the CSR is the comprehensive presentation of the trial plan, performance and all results of the trial and therefore the suitable QC basis. However, when no CSR is prepared, the content of the "Technical" Summary and the Lay Summary should be consistent as far as possible taking into consideration the regulatory differences in information required.

**Timelines**

EFGCP and EFPIA to submit the final draft GLSP recommendations document by early January to target final discussions and decision making by CTEG during the meeting on 4 February 2021.