23.11.2021

“Good Lay Summary Practice” Recommendations

Silvia Garcia
Senior Manager, Regulatory, Manufacturing and Drug Development,
European Federation of Pharma Industries and Associations (EFPIA)
Brussels, Belgium

Acknowledgement

This is a presentation made on behalf of the Roadmap Initiative to Good Lay Summary Practice Group, an initiative jointly led by EFGCP and EFPIA. 60+ industry, academia, patient and not for profit organisations joined forces to work out these Recommendations.

The draft proposal was reviewed, commented, amended, and adopted by CTEG, the European Commission's Expert Group on Clinical Trials, and published by the EU Commission in EudraLex Volume 10 on 04 October, 2021:

https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-10/glsp_en.pdf

Objectives

- Enable an agreed framework for the planning, delivery, translation and dissemination of Lay Summaries (LS) of clinical trial results as requested by EU Regulation 536/2014 (“Clinical Trials Regulation”)

- Enable a LS framework that can create a new level of transparency and interest in clinical research in patients (and the public) and that reliably fulfils the right of participants to learn about the results of the trial to which they donated their health

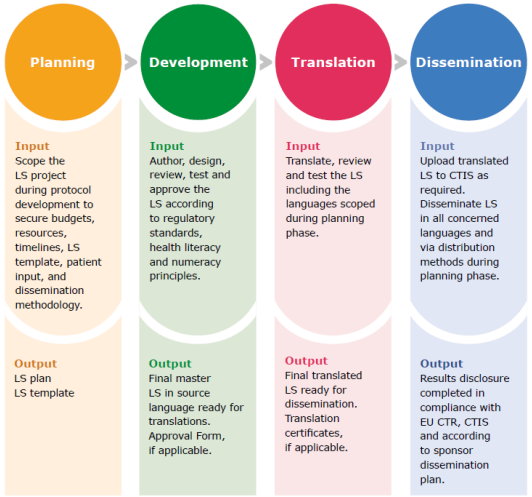
- Enable a LS framework that ensures comprehensive patient involvement in the overall process to enable optimal LS suitability for patients (and the public)

- Enable a LS framework that is suitable for multi-national trials with patients also from outside the EU and that enables the preparation of ONE global master LS

EU Clinical Trials Regulation No. 536/2014 (“EU CTR”)

- As of Feb 2022, EU CTR No.536/2014 will require trial sponsors to submit a « lay summary » or « LS » via CTIS portal, the single entry point for submitting CT information in EU and EMA will make information in CTIS publicly available

- The LS must be submitted:
  - No later than 12 months from the protocol –defined end of the clinical trial
  - 6 months for paediatric studies
  - Up to 30 months for non-therapeutic Phase 1 trials



Available Guidance and Experiences

- European Commission. 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. Version 2 (2017)

- Multi-Regional Clinical Trials (MRCT) - Return of Aggregate Results (2013, 2017); Tools and guidance for the clinical trial community

- Multi-Regional Clinical Trials (MRCT) and TransCelerate Inc: Draft Food and Drug Administration (FDA) Guidance on Provision of Plain Language Summaries (2017)

- TransCelerate Biopharma Inc.: Layperson Summaries of Clinical Trials: An Implementation Guide (2017)

- LS production and dissemination experience in large pharma companies

GLSP Development Process

- March 2019, Kick-off: Creation of 5 Task Forces, co-led by patients:
  - Document development
  - Patients' role in GLSP
  - Dissemination of LS
  - LS for academic studies
  - LS for paediatric studies

- December 2019: exploration of EU Commission's interest in a further recommendation document on Lay Summaries

- June to August 2020: Public consultation of draft GLSP

- July 9, 2021: Adoption of the GLSP by CTEG as a Commission recommendation

- October 4, 2021: Date of publication in EudraLex Volume 10

Underlying Ethical Principles

- The ethical obligation of all trial sponsors to enable reliable and comprehensive transparency by providing correct, comprehensive and objective trial result information
- Patients' right to be informed of the results of the research to which they contributed
- ALL participating patients' right on result information wherever they live
- ALL participating patients' and the public's right to receive that information in an objective, understandable way
- Reliable, fair and easy access to the result information for participants and the public
- Patients' right to contribute to the suitability of information that is of relevance to them

Scope and Intentions of GLSP

- Combination of legal obligations enforced by the EU CTR and recommendations based on experience across the diverse stakeholders

- Providing recommendations on how to enable patient engagement all through the LS process although it is acknowledged that sponsors' current resource and infrastructure limitations will only over time allow for a routine involvement of patients in the different steps

- Although the GLSP is founded on the EU CTR, it may also provide useful recommendations for lay summaries of trials in regions outside the EU/EEA territory

- LS recommendations in this document apply to aggregate clinical trial results only; therefore, return of patient-level data to individual trial participants is out of scope

- The need for specific skills and strategies for LS on paediatric trials is recognised and addressed in this document, although highlighting the limited experience available so far

- Although some shared principles may apply, other types of result information to the lay audience, such as plain language summaries of journal publications and conference abstracts, are out of scope

Good lay Summary Practice

- Structure:
  - GLSP Quick Guide
  - GLSP Handbook with Appendix on experiences and recommendations from Roadmap members
- Key strategies:
  - “Must” vs “Best Practice” facilitates step-wise implementation according to resource availability
  - Recommendations for paediatric LS in addition to recommendations on CTs in adults where possible
  - Patient involvement formally and boldly established
  - GLSP Quick Guide allows understanding the new concept for all involved in the broadest sense
  - GLSP Handbook gives detailed help to those who have to concretely enable planning, development, translation and dissemination of LS according to a multi-stakeholder agreed best practice standard

Good lay Summary Practice

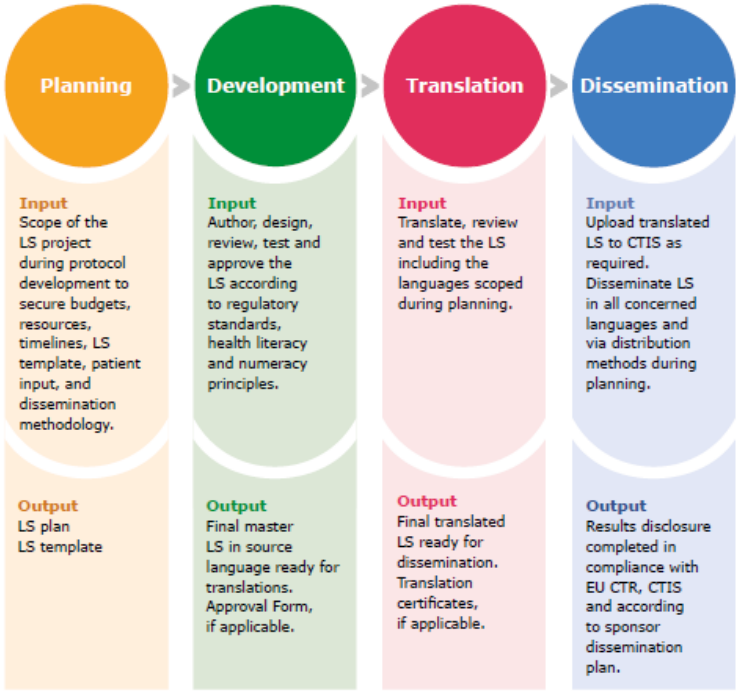


Figure 1: Flowchart of the Lay Summary Process

Document Icon Key	
§	Mandatory requirements under the EU CTR
	Recommendations on paediatric LS

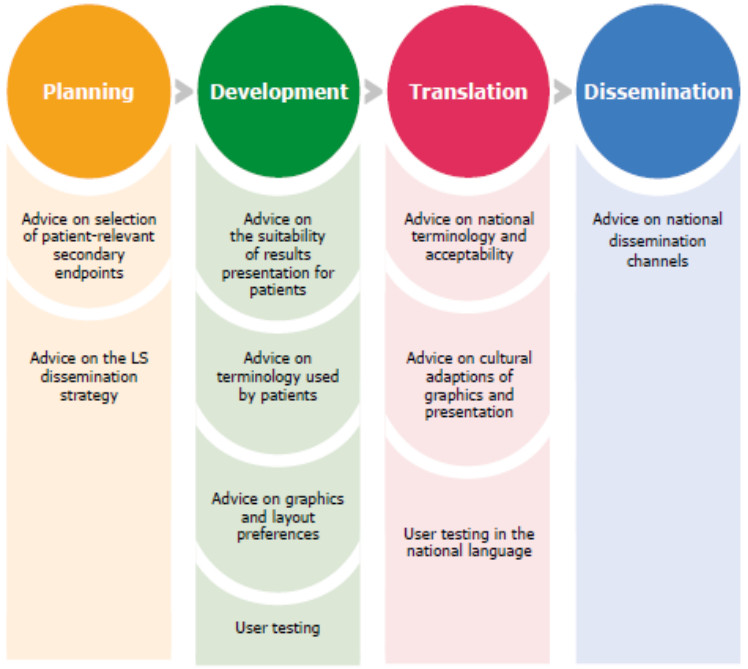


Figure 2.2: Patient Involvement during LS Steps

Individual patients	Individual patients are persons with personal experience of living with a disease. They may or may not have technical knowledge in research and development (R&D) or regulatory processes, but their main role is to contribute with their subjective disease and treatment experience.
Carers	Carers include persons supporting individual patients, such as family members, paid- or volunteer helpers.
Patient advocates	Patient advocates are persons who have the insight and experience in supporting a larger population of patients living with a specific disease. They may or may not be affiliated with an organisation.
Patient organisation representatives	Patient organisation representatives are persons who are mandated to represent and express the collective views of a patient organisation on a specific issue or disease area.
Patient experts	Patient experts, in addition to disease-specific expertise, have the technical knowledge in R&D and/or regulatory affairs through training or experience, for example EUPATI Fellows who have been trained by EUPATI on the full spectrum of medicines R&D.

Topics needing further discussions

- **GLSP recommendations for Indirect LS dissemination (public website)**
  - Uploading of the lay summaries into CTIS is mandatory
  - CTEG preferred option is Direct dissemination to trial participants
  - Beyond CTIS, sponsors to add an statement in the PIS/ICF that dissemination is according to sponsor policy , local laws and in a non-promotional manner
- As no broadly definition for “patient relevant” endpoints exists, sponsors may prefer to limit result presentation to the primary endpoints.
  - **What to present: only the primary endpoint or also “patient-relevant secondary endpoints” and how to define those?**
- CTIS does not foresee LS for uploaded interim results. **How to communicate those?**

Topics needing further discussions

- **Request to clarify the process for the LS translations as it has resources implications**
  - EU CTR does not request translations
  - At a minimum, LS best practice is to be provided in English and in the local official language of each of the countries where the CT took place (matching with PIS/ICF)
- The financial conditions in publicly funded trials do not foresee the need for funding LS dissemination after the end of the trial and thus the funding period. **How to change this?**
- There is very little experience with preparation and dissemination of LS for the patient in paediatric trials. **How to systematically develop and share this experience?**

Next steps

- Broad dissemination of the GLSP Recommendations
- Organisation of awareness and discussion opportunities on GLSP implementation, best ways to implementation and aspects that need further clarification
- Development of training material and opportunities on LS development and disseminations

Gràcies per la vostra atenció!

Gracias por vuestra atención!