23.11.21

Presentation of the GLSP
Recommendations from a patient perspective

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Acknowledgement

This is a presentation made on behalf of the Roadmap Initiative to Good Lay Summary Practice, 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

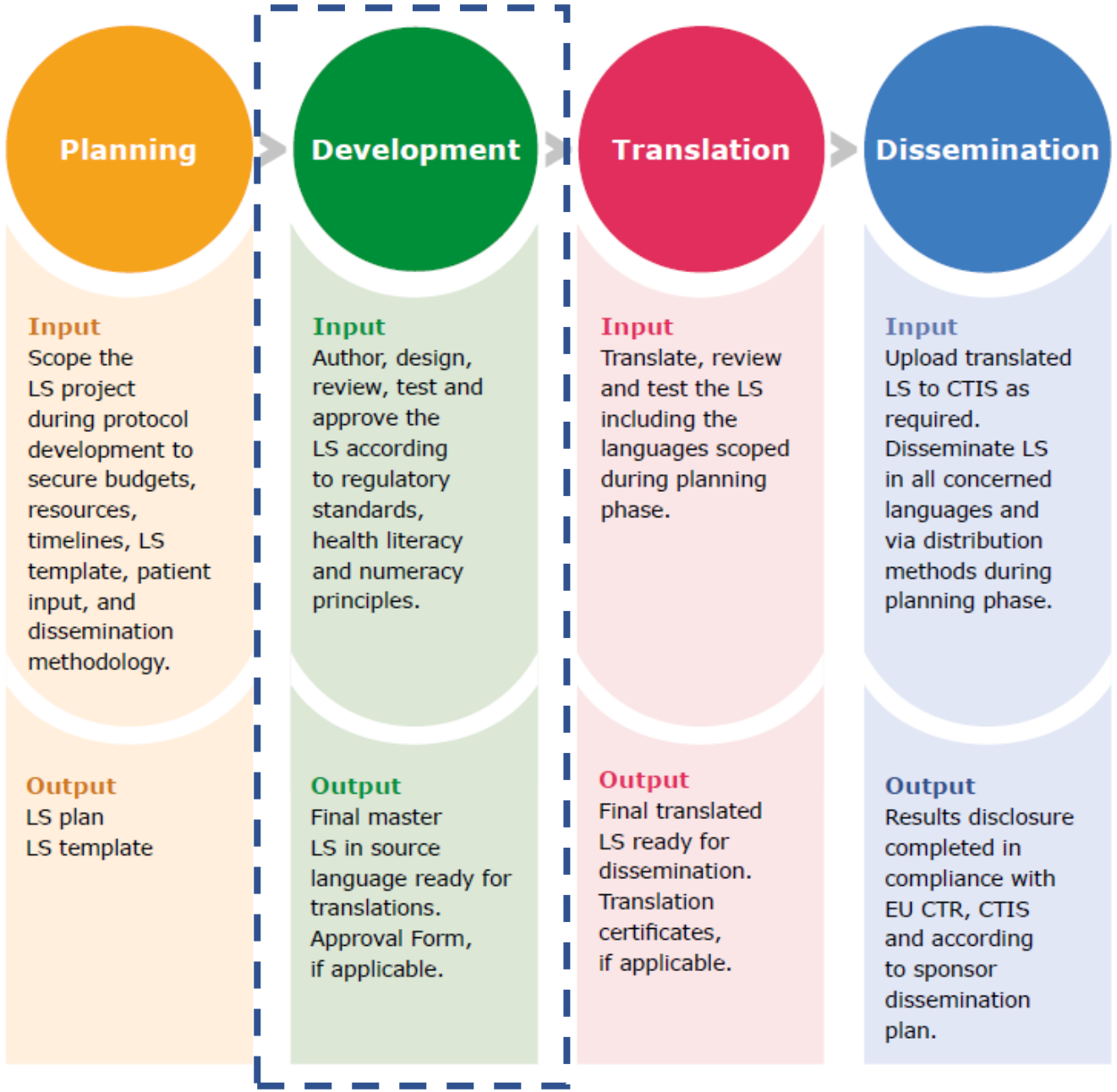
When involve the patients?

Patients Included is a Trademark of the REshape & Innovation Center

European Regulation 536/2014

- Article 37 requires trial sponsors to submit a “lay summary” that is understandable to laypersons.

- The LS must be submitted to the CTIS via the EU Portal no later than 12 months from the protocol-defined end of the clinical trial:
  - **6 months for paediatric studies**,
  - and up to 30 months for non-therapeutic Phase 1 trials.


Planning
Development
Translation
Dissemination
Input
Scope the LS project during protocol development to secure budgets, resources, timelines, LS template, patient input, and dissemination methodology.
Output
LS plan
LS template
Input
Author, design, review, test and approve the LS according to regulatory standards, health literacy and numeracy principles.
Output
Final master LS in source language ready for translations.
Approval Form, if applicable.
Input
Translate, review and test the LS including the languages scoped during planning phase.
Output
Final translated LS ready for dissemination.
Translation certificates, if applicable.
Input
Upload translated LS to CTIS as required.
Disseminate LS in all concerned languages and via distribution methods during planning phase.
Output
Results disclosure completed in compliance with EU CTR, CTIS and according to sponsor dissemination plan.

Planning of the LS should **start at the time of protocol preparation**. LS planning including **translations** should be **aligned with the preparation of the PIS and the ICF**, since these documents partly share content and readership.

Use/create of a LS template

Paediatric clinical trials LS should be accessible by young people from the age of 12 years upwards .

Important: create childfocused version of the LS for younger participants in addition to the version for the parents or legal representatives.

The trial participant must be informed during the Informed Consent process that a LS will be made available in the EU Database and when the LS will become available.

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Value of involving patients in the LS

Value of involving patients in the LS

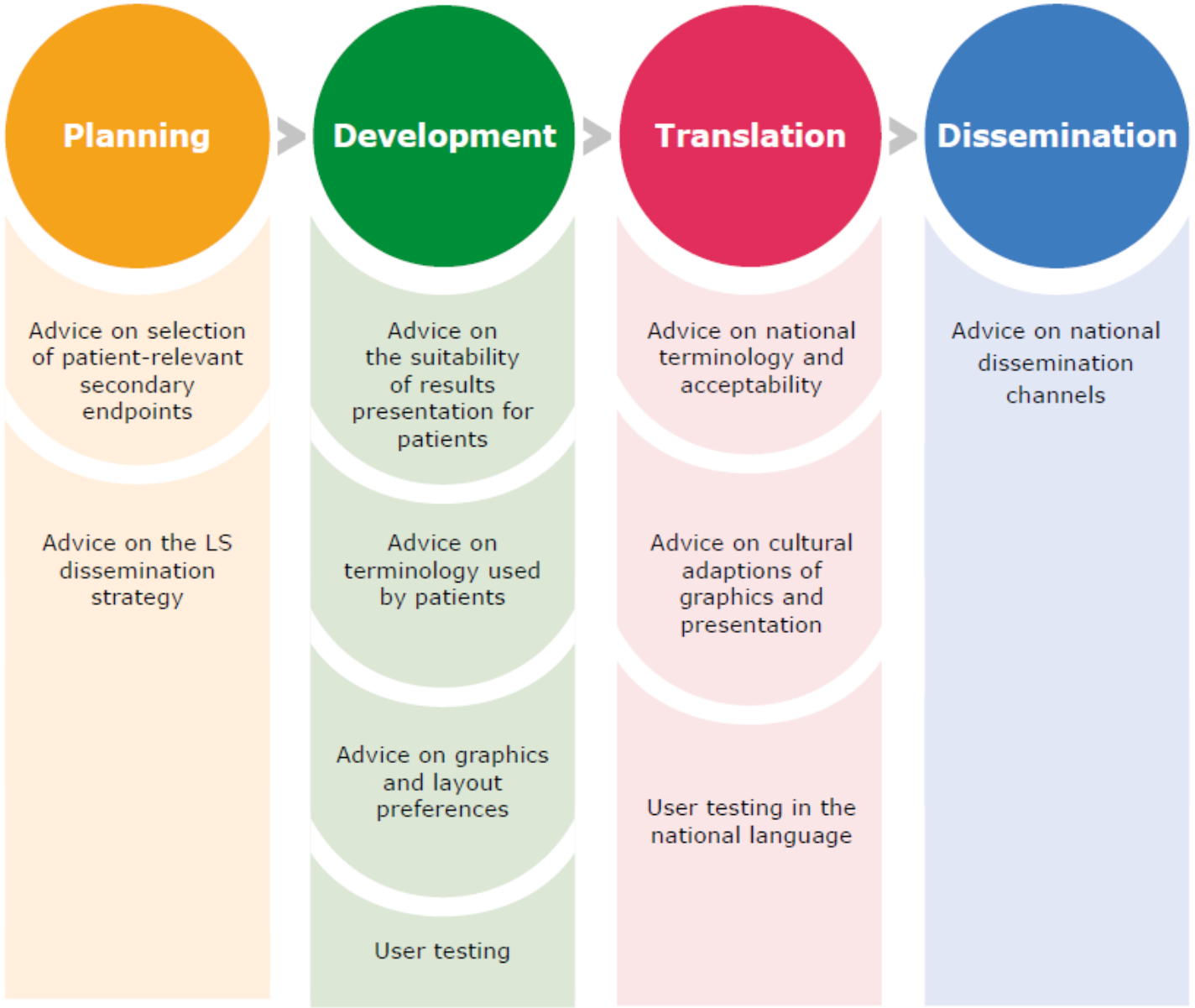
- Ensuring the **suitability** of the LS for patients, trial participants and the general public.
- Providing **unique perspectives** that may be different than those of researchers and healthcare providers.
- Insights into issues or **terminology** used in the patient community.

Patient-relevant secondary endpoints

- The LS should therefore reflect at a minimum the **results of the primary endpoint(s) and potentially patient-relevant secondary endpoints.**
- As no broadly accepted definition for “patient-relevant” endpoints exists and in order to keep the LS short, sponsors may prefer to limit result presentation to the primary endpoint(s).

Value of involving patients in the LS

- **Planning and preparation of this involvement** should start as early as possible and well before the end of the trial.
- **Planning of the LS**: Patient experts, patient advocates or patient organisation representatives.
- **Dissemination of the LS**: patients or representatives of the public without any familiarity with clinical trials for user testing of the master LS.


Planning
Development
Translation
Dissemination
Advice on selection of patient-relevant secondary endpoints
Advice on the LS dissemination strategy
Advice on the suitability of results presentation for patients
Advice on terminology used by patients
Advice on graphics and layout preferences
User testing
Advice on national terminology and acceptability
Advice on cultural adaptions of graphics and presentation
User testing in the national language
Advice on national dissemination channels

Health literacy is a challenge

“Write the way you talk”.

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Format of the Lay Summary (Patient preferences)

Format of the Lay Summary

- The EU Portal will accept LS to be uploaded in a **PDF file format**.
- This needs to be **suitable for print**.
- Include text and **figures as well as cartoons**.
- **Excludes videos and animations**.
- For paediatric trial result LS, sponsors are free to develop **videos and animations in their LS for separate dissemination**.

Patient-relevant secondary endpoints

The LS should therefore reflect at a minimum the results of the primary endpoint(s) and potentially patient-relevant secondary endpoints.

As no broadly accepted definition for “patient-relevant” endpoints exists and in order to keep the LS short, sponsors may prefer to limit result presentation to the primary endpoint(s).

Recruitment of patients

Recruitment of patients

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.

Recruitment of patients

- Consider the most suitable approach to **involving one or several patients** (different disease stages, ages, and scientific knowledge in the process of LS development, review/user testing, translation and/or dissemination.

- It is important to bear in mind that involving individual patients in LS activities does not ensure **patient representativeness**.

- Lay Paediatric public can be represented by Young Person's Advisory Groups (YPAGs): www.eypagnet.eu

Inviting patients as contributors of the LS process

An **information sheet written** in lay language should accompany the **invitation** to participants and describe:

- the project,
- the purpose of the patient contribution,
- the expected skills,
- time frame and
- the financial conditions of the collaboration.

Compensation of Patients and Public Contributors

6. Participación en la elaboración y redacción de resúmenes ejecutivos de los ensayos clínicos (lay summary).

Específicamente, los pacientes pediátricos enfatizan la importancia de usar **tablas, gráficos o infografías en color** que ayuden a comprender la información, así como de disponer de un **video resumen** (siempre respetando los criterios para la mejor **accesibilidad** posible) con el contenido que integra la versión escrita del lay summary, ya que el formato visual facilita el proceso de comprensión de la información.

Thank you so much!

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