Principles and best practices for lay summaries

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What are lay summaries?

Lay Summaries inform patients and the general public about results of a clinical study

Need to be short, factual, and non-promotional

Are easy to understand for readers with low reading skills

Express gratitude to the patients who participated

Are available in all the languages of the trial

Provide an excellent opportunity to engage with patients, physicians, and the public!

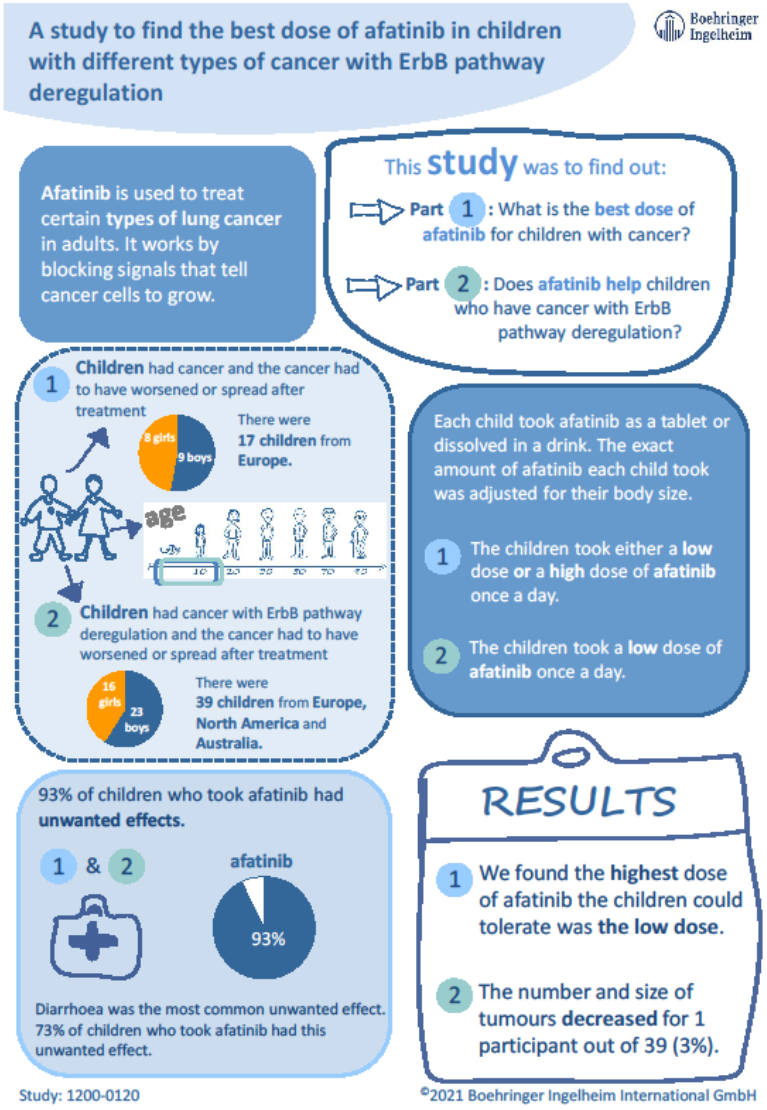
Principles

- Lay Summaries are a legal requirement **for all clinical trials** with a trial site in the EU.
- Lay summaries must be uploaded to EU portal **12 months** after end of study (6 months for studies in children).
- Content of the lay summaries must follow the **legal requirements**, should consider the available guidance, and be **strictly non-promotional**.
- The target audience of lay summaries is the **general public**! Lay summaries should be understandable for everybody.
- Lay summaries should be provided in **all languages** of the trial participants.
- Sponsor need a **consistent approach** for lay summaries across all studies.
- Sponsors should form a **dedicated team** for lay summaries that entails plain language experts.
- **Patient involvement** is important and needs to be defined and organised.

Annex V of the EU-regulation – content of lay summaries

1. Clinical trial identification (including title of the trial, protocol number, EU trial number and other identifiers);
2. Name and contact details of the sponsor;
3. General information about the clinical trial (including where and when the trial was conducted, the main objectives of the trial and an explanation of the reasons for conducting it);
4. Population of subjects (including information on the number of subjects included in the trial in the Member State concerned, in the Union and in third countries; age group breakdown and gender breakdown; inclusion and exclusion criteria);
5. Investigational medicinal products used;
6. Description of adverse reactions and their frequency;
7. Overall results of the clinical trial;
8. Comments on the outcome of the clinical trial;
9. Indication if follow up clinical trials are foreseen;
10. Indication where additional information could be found.

Example lay summary: pediatric trial



C:\Data\Working data\SAKK\Lay Summary_1200-0120 English.pdf

Planning of lay summaries

- Plan for the entire lay summary process and create a Standard Operating Procedure (SOP) that covers writing, review, and dissemination of lay summaries
- Develop a general template for lay summaries that includes graphics and icons
- Provide budget and resources for the production of lay summaries including cost of translation and dissemination
- Develop a strategy for a comprehensive involvement of patients in the production of lay summaries

Development and writing of lay summaries

- Adopt the Good Lay Summary Practice (GLSP) guidance for the creation and the content
- Establish a team with the appropriate skills:
  - Knowledge of clinical research, guidance on lay summaries
  - Lay communication, lay language writing and editing
  - Visual design, good graphic design principles
  - Translation skills and user testing expertise
- Consider health literary and numeracy limitations in the audience(s) for the presentation of text and data

Development and writing of lay summaries

- Ensure that the content and presentation of data is balanced and strictly non-promotional
- Apply appropriate design to make lay summaries attractive:
  - Use headings and subheadings
  - Make adequate use of white space
  - Develop simple and clear graphics: 1 message per graph
- Prepare internal reviewers of lay summaries for the task:
  - Provide training on purpose and design
  - Give reviewers clear guidance on the objective of their review
- Consider development of lay summaries for children

Translation of lay summaries

- Consider translations as a **core activity** in the provision of lay summaries
- Plan translations early in the development of lay summaries:
  - Consider the Patient Information Sheet and the Informed Consent Form as sources
  - Ensure that translations are accurate and in a language that is considered adequate by (local) readers
- Consider process of back-translation and local approval of lay summaries to ensure optimal quality

Dissemination of lay summaries

- Uploading of the lay summaries into the EU portal is mandatory!
- Sponsors are encouraged to develop other dissemination pathways and plan them carefully
- Optional dissemination methods include:
  - Direct dissemination via mail, postal service, or by the investigator
  - Indirect dissemination via a public website
  - Combination of indirect and direct dissemination

Dissemination of lay summaries

Direct dissemination

- Mail of lay summary print-out or distribution of lay summary via the trial site
- + more personal approach
- + participant can ask questions
- - increases burden on site
- - has cost implications
- Creates logistic challenges

Indirect dissemination

- Posting of lay summary on a public website
- + easy access for all audiences
- + opportunity to provide lay summaries in different languages
- - unable to respond to questions
- Need for non-promotional content of website

Sources

Guidelines

- Good lay summary practice. 2021 Microsoft Word - GLSP_EudraLex_Submitted to CTEG_24Sep2021_FINAL-B4 (europa.eu)
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