The challenge of writing scientific texts in plain language – the problem of oversimplification

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What are lay summaries ?

Lay summaries are meant to inform the general public and patients about the results of a clinical study.

They should

- Provide the key data to understand a clinical study: demographics, patient flow, efficacy and safety results
- Be short and factual
- Be easy to understand for readers with low literacy skills
- Express gratitude to the patients who participated
- Be available in translated versions
- Be available 1 year after the end of the study
- Lay summaries need to be non-promotional !

REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 16 April 2014

on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

(39) The sponsor should submit a summary of the results of the clinical trial together with a summary that is understandable to a layperson, and the clinical study report, where applicable, within the defined timelines.

(67) The EU database should be publicly accessible and data should be presented in an easily searchable format, with related data and documents linked together by the EU trial number and with hyperlinks, for example linking together the summary, the layperson's summary, the protocol and the clinical study report of one clinical trial, as well as linking to data from other clinical trials which used the same investigational medicinal product.

§37 Irrespective of the outcome of a clinical trial, within one year from the end of a clinical trial in all Member States concerned, the sponsor shall submit to the EU database a summary of the results of the clinical trial. The content of that summary is set out in Annex IV. It shall be accompanied by a summary written in a manner that is understandable to laypersons. The content of that summary is set out in Annex V.

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.

Expectations vs. limitations of a summary of one study

What patients want to know:

Is drug A **better** than drug B?
Will drug A help **me**?
Is drug A **safe**?

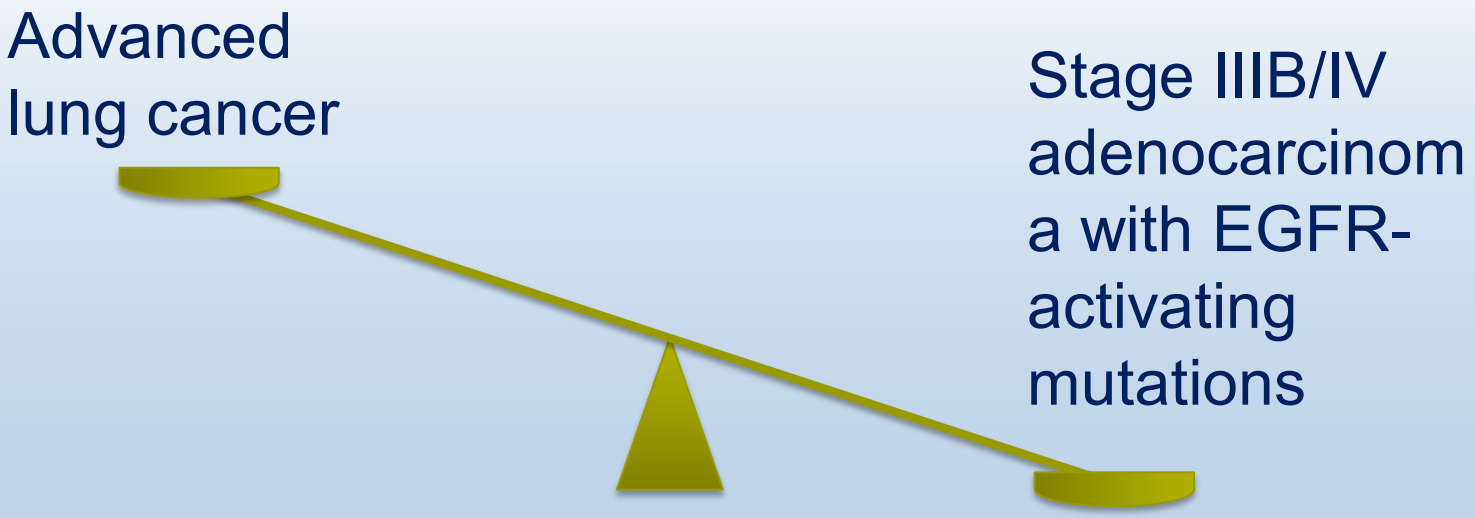
What we can say based on a single study:

At time point X, patients in the study who took drug A had on average lower values for parameter Y than patients who took drug B.

Diverse audiences – appropriate level of detail?

Member of the general public; low reading skills, no prior knowledge of the study, indication, or clinical research

An educated patient looking for information beyond the basics



Study primary endpoint – what the study is about

Scientific description

Time to the first occurrence of any of the following: CV death, non-fatal MI or non-fatal stroke (adjudication-confirmed).

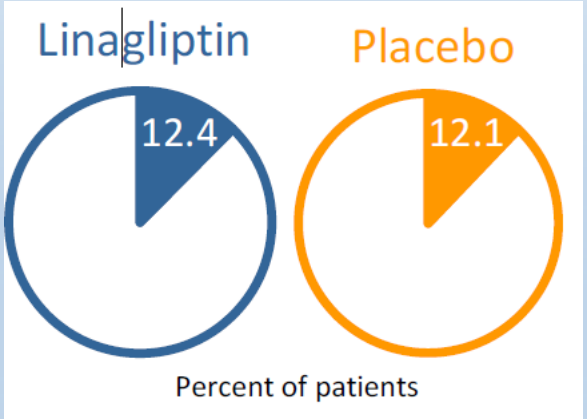
Results:

There were 434 patients (12.4%) with an event in the linagliptin group and 420 patients (12.1%) in the placebo group. The hazard ratio (HR) based on Cox proportional hazards regression model for linagliptin vs. placebo was 1.02 (95% CI 0.89, 1.17). Linagliptin was therefore demonstrated to be non-inferior to placebo with an upper bound of the 95% CI of below 1.3 and not superior to placebo.

Lay summary

Is linagliptin as safe as placebo if added to one‘s standard meds in regards to heart attack or stroke or cardiovascular death?

The percentage of patients with heart attack or stroke or cardiovascular death was **similar** for linagliptin and placebo.



“as simple as possible, but not simpler”

Challenges	Solutions
Patient expectations	Disclaimer highlighting limitations of document
Right level of detail	Testing with patient groups, development of supplementary resources, use of graphics
Description of research question and results	Use of broader, well-known terms, truthful transfer of scientific results into lay language, use of infographics
Timing	Post lay summary at the same time as the scientific results
Apparent differences between scientific documents and lay summary	Include definition of purpose in lay summary, refer to scientific documents for further detail

An example: CARMELINA Study

More examples at:
https://trials.boehringer-ingelheim.com/trial_results/clinical_trials_overview.html