Plain language summaries

Lay summaries for Clinical Trials in EU

Excelya Medical Affairs Department
November 2024

LAY SUMMARIES

With the implementation of the new EU Clinical Trials Regulation (CTR) and the launch of the dedicated website for clinical trials, Clinical Trials Information System (CTIS), there has been a major focus on increasing the transparency of clinical trials and engaging the scientific community as well as the public (lay people).
Clinical trial Sponsors are, therefore, requested to provide easy-to-read comprehensive lay summaries for the design and conclusions of all clinical trials conducted in the EU in each local language.

WHAT IS A LAY SUMMARY, AND WHAT IS ITS PURPOSE?

A lay summary, sometimes called plain language summary (PLS) or lay summary (LS), is a document that explains the details of a research study in a simple, manner and using plain terms, so that it can be easily understood by the general public, including trial participants and caregivers.
The purpose of a lay summary is to facilitate access to the information on the research study, including its purpose, objectives, methods, and results, ensuring that non-specialists can understand what was done, why it was done, and what was discovered. [4]

WHEN SHOULD LAY SUMMARIES BE SUBMITTED?

Lay summaries are submitted for the protocol synopsis and the trial's final and, if applicable, interim results. Protocols provide detailed information on the conduct of the clinical trial that is understood by researchers.
The lay protocol synopsis (PLPS or LPS) has to be submitted as part of the initial application for clinical trial approval. The lay summaries for the results reporting should be submitted to the CTIS no later than 12 months from the end of the clinical trial.
For the UK, the Medicines and Healthcare Products Regulatory Agency (MHRA) requires that a lay protocol synopsis is also submitted to the International Standard Randomised Controlled Trial Number (ISRCTN) registry.

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WHAT SHOULD BE INCLUDED IN THE LAY SUMMARY?

The expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use has issued recommendations for the preparation of lay summaries depending on the targeted audience (Good Lay Summary Practice). These recommendations should be strictly adhered.

A lay protocol summary should contain the following:

- Clinical trial title and unique EU number
- Clinical trial rationale (objectives, main endpoints)
- Information on clinical trial design, including procedures
- Information on participants who are eligible to participate in the clinical trial
- Information on the investigational drug
- Implications of the trial for the public, such as the expected benefit and potential risks

The lay summary for the final results should contain the following:

- Information on the clinical trial design (title, rationale, objectives, and participants).
- Information on the investigational drug and trial procedures.
- Summary of the clinical trial's overall results
- A clear description of adverse reactions and their frequency.
- The significance of the clinical trial findings and their implications for the public.

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ADVANTAGES OF LAY SUMMARIES

Lay summaries benefit patients, sponsors, and decision-makers as follows:

- Lay summaries make research findings accessible to a broader audience, ultimately increasing public awareness.
- Clear and understandable lay summaries foster transparency and build trust between clinical research stakeholders and the public.
- The transparency and accessibility of lay summaries can help promote patient recruitment in ongoing trials as well as represent a comprehensive strategy to engage enrolled patients in the trials.
- Lay summaries make it easier for health professionals, commissioners, policymakers, and funders to access a succinct report of the clinical trial findings.

By increasing awareness and health literacy among the general public early in drug development, lay summaries may promote patient-centric clinical research and empower patients in shared decision-making (SDM). However, certain barriers exist that include ambiguity in the available guidance documents, lack of incentives, and concerns of researchers regarding the preparation of content meant for the general public.

EXCELYA AS A PARTNER FOR LAY SUMMARY DEVELOPMENT

At Excelya, we understand the critical role that lay summaries play in promoting transparency and public trust in clinical research. Our goal is to provide trial Sponsors with comprehensive, high-quality lay summaries that make trial findings accessible to all.
With a dedicated team of experts in medical writing with experience across all therapeutic areas and phases (I, II, III, and IV), Excelya can:

- Introduce high-scientific content into plain language that is easily accessible to lay persons and non-scientific readers in compliance with Good Lay Summary practice guidelines.
- Effectively provide translation of the lay summaries in all required languages

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Lay summaries represent a valuable resource for increasing the visibility and impact of your research. Excelya can be a one-stop partner for the coherent and cost-effective development of protocol and protocol lay summary or end-of-trial clinical report development and corresponding lay summary in compliance with regulatory requirements or undertake the review of these documents.

For further information, please contact us at:
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