Luto.

# Clinical trial lay summaries.

We make your clinical trial study information easy to understand. For everyone.

Making health information clear

luto.co.uk

# You've completed your clinical trial. Now what?

Well, according to a new EU ruling - EU Clinical Trials Regulation No. 536/2014 - all clinical trial sponsors must provide a lay summary of their results within one year of completing the trial.

Patient-centricity isn't just about meeting regulatory requirements though, but going a step further and creating something truly 'lay friendly'.

We can get you there, no matter what stage of the process you are at.

# What is a clinical trial lay summary?

A brief outline of the design and results of clinical studies written using plain English is called a lay summary. These summaries (also called layperson summary, plain language summary, lay language summary, simple language summary, and trial results summary) are intended to make the clinical results of these studies understandable and accessible to patients and caregivers.

# Article 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.

> It shall be accompanied by a summary written in a manner that is understandable to laypersons.

## 10 things you need to include in your lay summary

- Clinical trial identification (including title of the trial, protocol number, EU trial number and other identifiers)
- Description of adverse reactions and their frequency
- Name and contact details of the sponsor
- Overall results of the clinical trial
- General information about the clinical trial
- Comments on the outcome of the clinical trial
- Population of subjects
- Indication if follow-up clinical trials are foreseen
- Investigational medicinal products used
- Indication where additional information could be found

EU Clinical Trials Regulation No. 536/2014, Annex V.

# How important is patient-centricity to you?

Though not mandated, guidance recommends seeking patient input when creating your lay summaries.

We have access to a diverse range of volunteers, who can provide you with the evidence needed to tailor your lay summaries.  Who better to speak to than the people who will read them?

Patient panels, co-design workshops, and user tests are some of the ways we regularly engage with patients.

Luto believes in using real-world evidence alongside our wealth of experience – sometimes it is impossible to predict exactly how patients will interpret the information.

# Is your patient-facing information as lay-friendly as it could be?

Patients should be involved when creating your materials, and ideally at several points along the way. As health literacy consultants, Luto also works with pharmaceutical companies to advise on using lay-friendly language and design for a wide range of materials.

It isn't just the summary of the clinical trial that is important, but the information sheets and consent forms that volunteers taking part will need to understand.

You should be considering how understandable your materials are before you even start Phase 1 of a clinical trial.

We can help by using our expertise in lay writing to refine the information you will give to volunteers.

# layperson

**/leɪpɜːrsn/**

an individual who does not have a formal education in a relevant field of healthcare or medical discipline

(The EU MDR, 2017/745)

# How we can help.

Luto works with pharmaceutical companies to develop their lay summary strategies and provide in-house training. We can also provide a full design service for lay summary materials. Here are some of the ways we can help you:

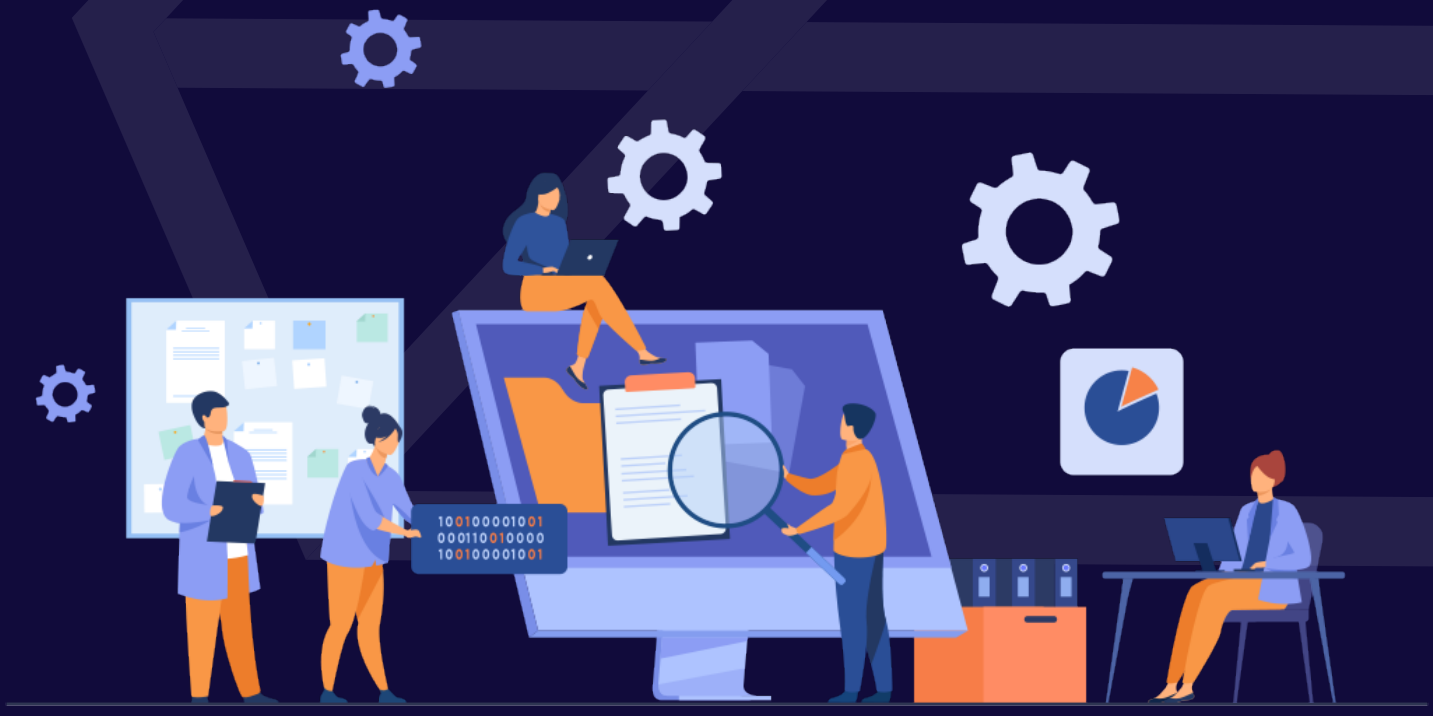
| What you need to do | How we can help |
|---|---|
| **Plan your lay summary development process** | • Develop a tailored plan to meet your budget and timelines<br>• Meet your needs for regular development of lay summaries<br>• Create templates for your future lay summaries |
| **Turn scientific language into lay language** | • We are experts in writing for lay people, ensuring information is understood by all<br>• Write your lay summary from your clinical study report synopsis<br>• Make sure statistics and numerical information are presented using good practice<br>• Review and improve your existing lay summaries |
| **Use lay-friendly design worthy of the content** | • Apply our expertise in graphic design and layout to present your lay summary in a clear and effective way<br>• Work to your brand guidelines |
| **Translate your lay summary** | • We can facilitate the translation of your lay summary into other languages<br>• Ensure good practice in readability carries across to your translated materials |

# Our services

- Planning and strategy
- Writing and design
- Full content review for existing lay summary drafts
- User testing
- Expert patient reviews, patient panels, and co-design workshops
- Template creation
- Translation
- Development and review of consent forms and participant information sheets
- Design of post trial dissemination materials

Visit our website for more information and useful links:

**luto.co.uk**



# Let's work together.

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