Writing lay summaries: What medical writers need to know

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Abstract
Lay summaries are critical for building public trust in clinical research and therefore for recruiting patients. They are also an important part of efforts to improve data transparency. Due to new global regulations, lay summaries will soon probably become mandatory for all clinical studies. Medical writers should therefore be aware of the regulations and essential content of lay summaries. Using a case study of a published lay summary, this article discusses best practices, including the appropriate target audience, language, and data and visual presentation.

What are lay summaries?
Understanding clinical studies is important not only for healthcare professionals but also patients (see Box 1).[1,2] A major concern, however, is whether the participants can understand the technical terms employed. Lay summaries were created to address this need. They briefly explain the results of a clinical study in non-technical language. This allows patients to be informed of what happened in the study, helps to recruit participants for future trials, and reinforces patient trust in clinical research.[2] Lay summaries are also important for transparency and thereby help improve the overall quality of clinical research. The benefits of lay summaries are illustrated in Figure 1.

Box 1. Public attitude toward clinical studies
A global survey in 2017 of more than 12,000 respondents (including patients and the general public) by the the Center for Information and Study on Clinical Research Participation found that 85% of the public valued clinical studies for developing new medicines and considered clinical studies to be safe (90%).[3] The survey also found that 84% considered it important to be aware of the clinical studies being conducted in their communities, and 91% believed that it is important to receive a summary of the study after they participated in a clinical study.

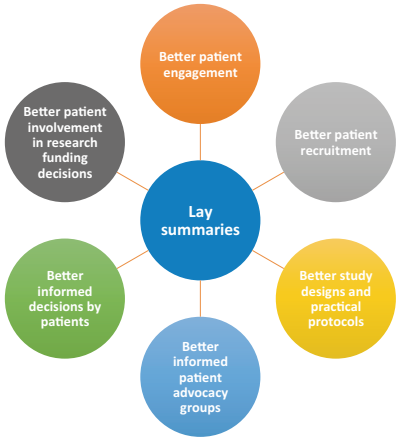


Figure 1. Benefits of preparing lay summaries.

Regulatory requirements of lay summaries
The Declaration of Helsinki[4] considers the dissemination of clinical study results crucial. It states that "*all medical research subjects should be given the option of being informed about the general outcome and results of the study*".

Further, EU Clinical Trials Regulation 536/2014 states that sponsors should provide a summary of clinical trial results in a format that can be understood by a lay audience (i.e., lay summaries) within a year after a trial is

completed.[5,6] Although the regulation was adopted in 2014, it is expected to not be fully applied until 2019 when the EU database that includes lay summaries will become fully functional.[7] In the US, lay summaries are not included in the Final Rule on registering clinical trials and submitting results, although the US FDA encourages providing lay summaries to the participants of clinical studies.[8,9]

Since the regulations on lay summaries are about to change, various organisations and pharmaceutical companies have collaborated to meet the standards. Since 2011, the Center for Information & Study on Clinical Research Participation, in association with several global pharmaceutical companies, has been helping to translate the technical results of clinical studies into lay summaries.[10] Also, TrialScope, in partnership with AstraZeneca, recently launched a Trial Results Summaries Portal where sponsors can post lay summaries for study participants and the general public.[11]

Due to changing regulations, and growing interest of patients (and the general public), lay summaries are becoming mandatory worldwide. Medical writers therefore should be aware of their content and style.

Key elements of a lay summary

According to Annex V of the EU Clinical Trials Regulation, lay summaries should include 10 essential elements describing details of the clinical study design and conduct, the medicinal product tested, and overall results.[5] These are summarised in Box 2.

However, Annex V does not provide explanations or instructions about the format, length, or language. To fill these gaps, a task force has assembled more detailed guidance entitled "Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use".[6] This guidance not only gives an explanation of the 10 essential elements but also provides some instructions on writing style, language, numbers, visuals, and other important aspects of a lay summary.

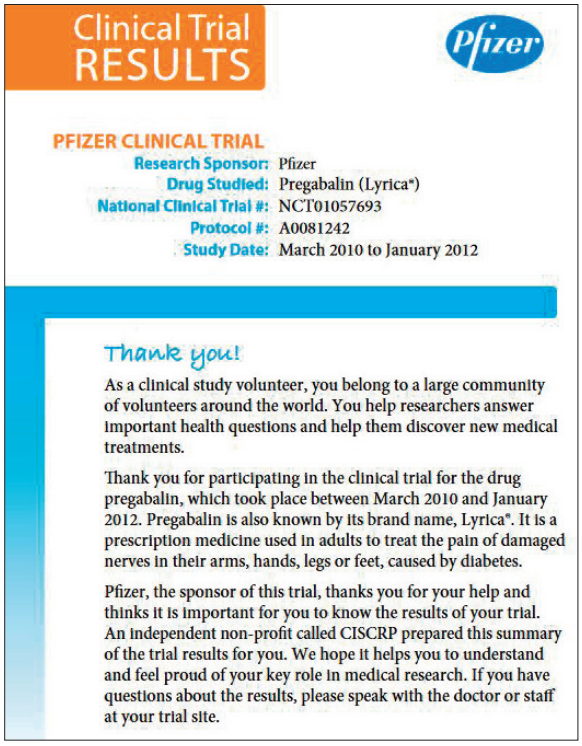
Content of a lay summary: A case study

To illustrate the type of information to be included in each section, we studied a published lay summary on pregabalin,[12] a drug for treating diabetic neuropathy.[13]

Title page

The lay summary starts with a title page (Figure 2) that provides basic information about the study like the sponsor, drug studied, trial number, and study dates. Identifying information for the study is at the top of the page, and following a "thank you" message, the study is introduced:

"Thank you for participating in the clinical trial for the drug pregabalin, which took place between March 2010 and January 2012."


Clinical Trial RESULTS

Pfizer

PFIZER CLINICAL TRIAL

Research Sponsor: Pfizer
Drug Studied: Pregabalin (Lyrica®)
National Clinical Trial #: NCT01057693
Protocol #: A0081242
Study Date: March 2010 to January 2012

Thank you!

As a clinical study volunteer, you belong to a large community of volunteers around the world. You help researchers answer important health questions and help them discover new medical treatments.

Thank you for participating in the clinical trial for the drug pregabalin, which took place between March 2010 and January 2012. Pregabalin is also known by its brand name, Lyrica®. It is a prescription medicine used in adults to treat the pain of damaged nerves in their arms, hands, legs or feet, caused by diabetes.

Pfizer, the sponsor of this trial, thanks you for your help and thinks it is important for you to know the results of your trial. An independent non-profit called CISCRP prepared this summary of the trial results for you. We hope it helps you to understand and feel proud of your key role in medical research. If you have questions about the results, please speak with the doctor or staff at your trial site.

Figure 2. A typical lay summary: first page.
Source: Center for Information & Study on Clinical Research Participation. [12]

The section then describes the drug and its use in a non-technical language:

"Pregabalin is also known by its brand name, Lyrica®. It is a prescription medicine used in adults to treat the pain of damaged nerves in their arms, hands, legs or feet, caused by diabetes."

This is followed by a simple thank you note from the sponsor that also highlights the importance of patients in clinical research, building trust and confidence in the study.

"Pfizer, the sponsor of this trial, thanks you for your help and thinks it is important for you to know the results of your trial…We hope it helps you to understand and feel proud of your key role in medical research."

Second page

The second page of this lay summary (Figure 3) describes the study rationale and design and provides an explanation of what has occurred since the study was completed.

What's happened since my trial ended?

This section gives an overview of study duration, number of participants, and what was done when the study ended:

"The entire study took almost 2 years to finish, and included 665 volunteers at 129 locations in

Box 2. The 10 essential aspects of a lay summary [6]

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.

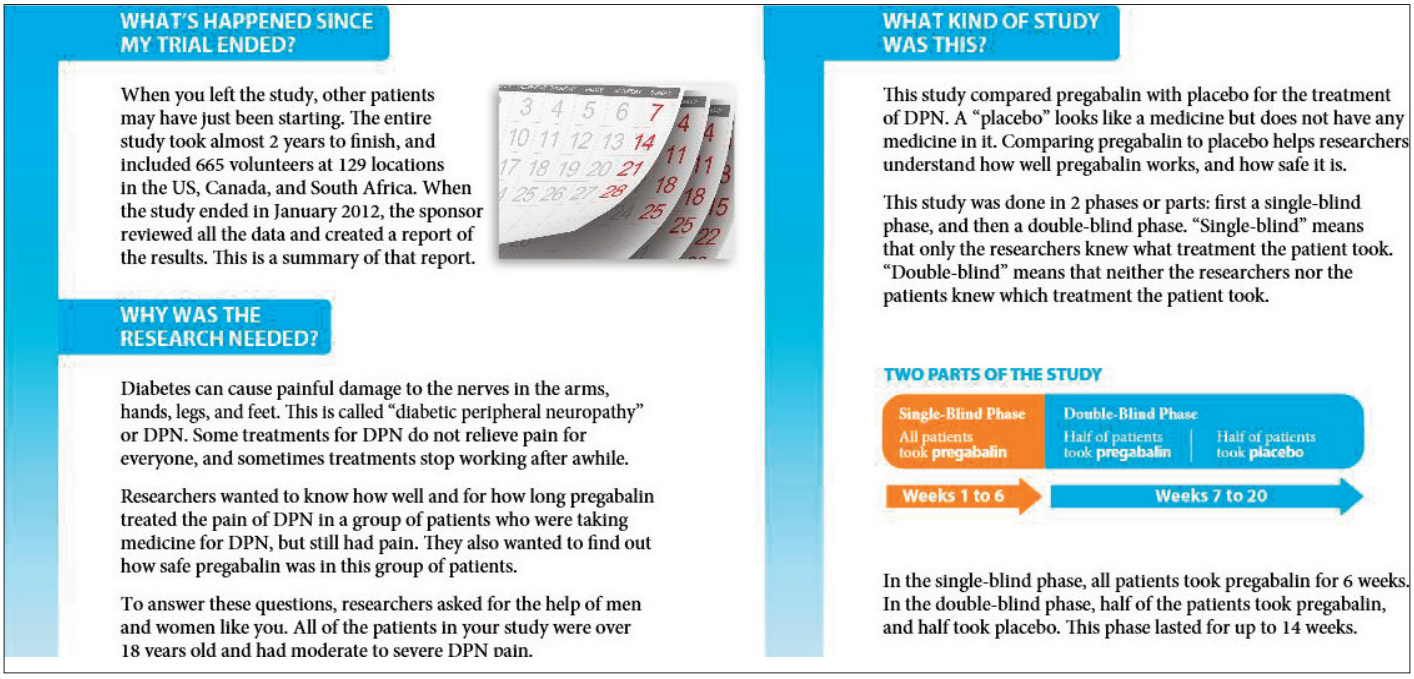


Figure 3. A typical lay summary: second page. Source: Center for Information & Study on Clinical Research Participation. [12]

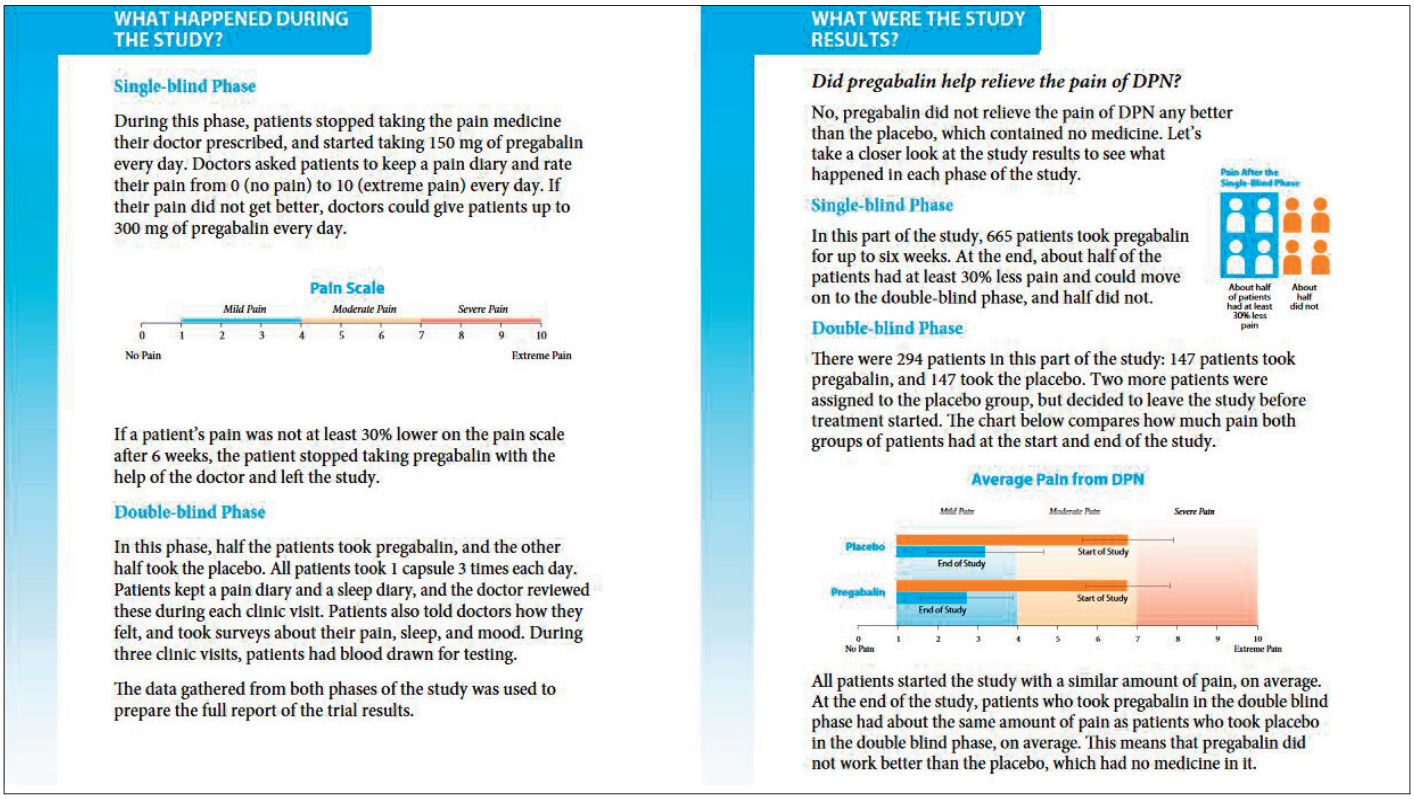


Figure 4. A typical lay summary: third page. Source: Center for Information & Study on Clinical Research Participation. [12]

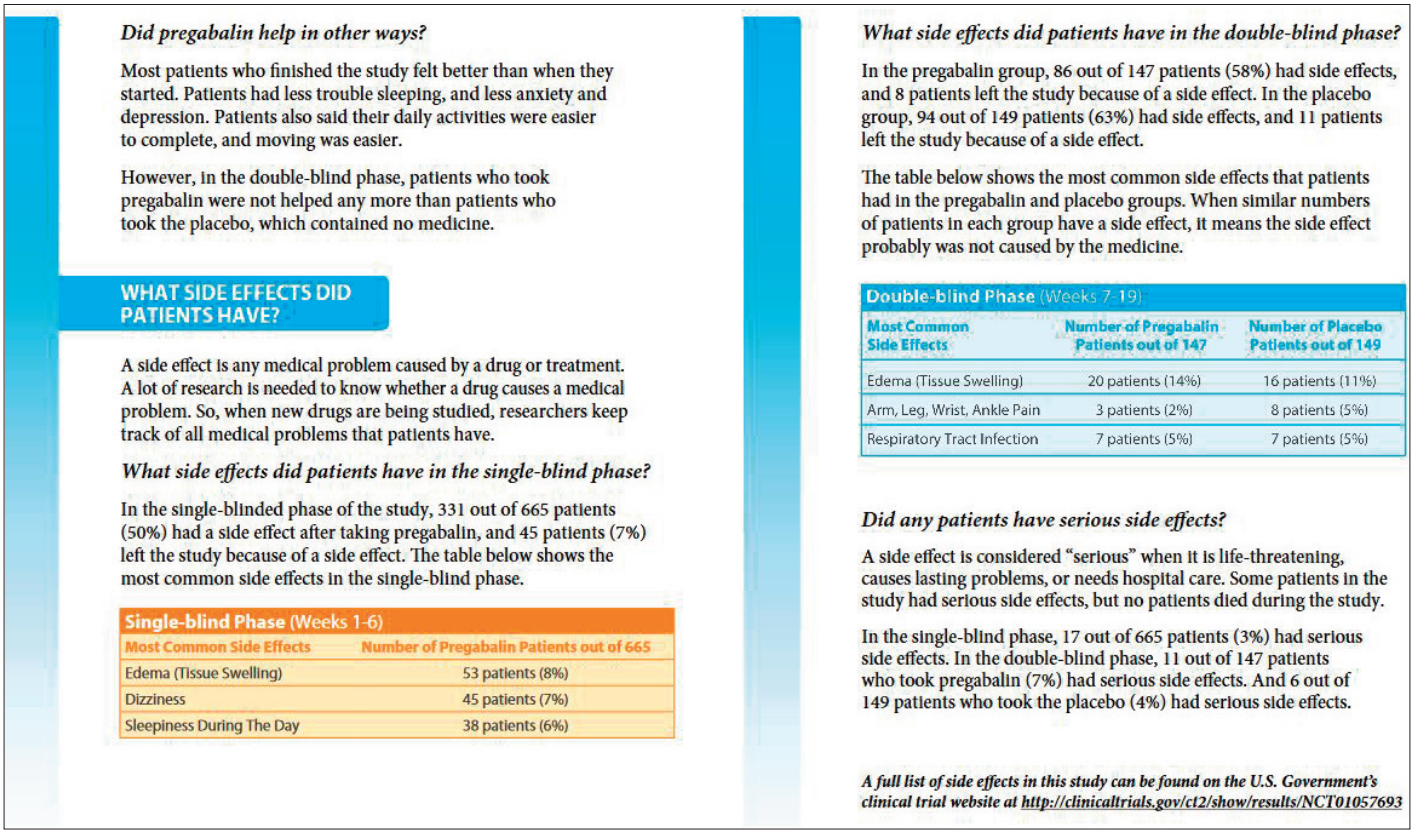
the US, Canada, and South Africa. When the study ended in January 2012, the sponsor reviewed all the data and created a report of the results."

Why was the research needed?

This section describes the rationale for the study in language that can be understood by a layperson:

"Diabetes can cause painful damage to the nerves in the arms, hands, legs, and feet. This is called diabetic peripheral neuropathy (DPN). Some treatments for DPN do not relieve pain for everyone, and sometimes treatments stop working after a while."

The section also explains what the disease is and why the sponsors are interested in performing this study:



Did pregabalin help in other ways?

Most patients who finished the study felt better than when they started. Patients had less trouble sleeping, and less anxiety and depression. Patients also said their daily activities were easier to complete, and moving was easier.

However, in the double-blind phase, patients who took pregabalin were not helped any more than patients who took the placebo, which contained no medicine.

WHAT SIDE EFFECTS DID PATIENTS HAVE?

A side effect is any medical problem caused by a drug or treatment. A lot of research is needed to know whether a drug causes a medical problem. So, when new drugs are being studied, researchers keep track of all medical problems that patients have.

What side effects did patients have in the single-blind phase?

In the single-blinded phase of the study, 331 out of 665 patients (50%) had a side effect after taking pregabalin, and 45 patients (7%) left the study because of a side effect. The table below shows the most common side effects in the single-blind phase.

Single-blind Phase (Weeks 1-6)

Most Common Side Effects	Number of Pregabalin Patients out of 665
Edema (Tissue Swelling)	53 patients (8%)
Dizziness	45 patients (7%)
Sleepiness During The Day	38 patients (6%)

What side effects did patients have in the double-blind phase?

In the pregabalin group, 86 out of 147 patients (58%) had side effects, and 8 patients left the study because of a side effect. In the placebo group, 94 out of 149 patients (63%) had side effects, and 11 patients left the study because of a side effect.

The table below shows the most common side effects that patients had in the pregabalin and placebo groups. When similar numbers of patients in each group have a side effect, it means the side effect probably was not caused by the medicine.

Double-blind Phase (Weeks 7-19)

Most Common Side Effects	Number of Pregabalin Patients out of 147	Number of Placebo Patients out of 149
Edema (Tissue Swelling)	20 patients (14%)	16 patients (11%)
Arm, Leg, Wrist, Ankle Pain	3 patients (2%)	8 patients (5%)
Respiratory Tract Infection	7 patients (5%)	7 patients (5%)

Did any patients have serious side effects?

A side effect is considered "serious" when it is life-threatening, causes lasting problems, or needs hospital care. Some patients in the study had serious side effects, but no patients died during the study.

In the single-blind phase, 17 out of 665 patients (3%) had serious side effects. In the double-blind phase, 11 out of 147 patients who took pregabalin (7%) had serious side effects. And 6 out of 149 patients who took the placebo (4%) had serious side effects.

A full list of side effects in this study can be found on the U.S. Government's clinical trial website at http://clinicaltrials.gov/ct2/show/results/NCT01057693

Figure 5. A typical lay summary: fourth page. Source: Center for Information & Study on Clinical Research Participation. [12]

"Researchers wanted to know how well and for how long pregabalin treated the pain of DPN in a group of patients who were taking medicine for DPN, but still had pain. They also wanted to find out how safe pregabalin was in this group of patients."

What kind of study was this?

Because patients and the general public will not understand the study design, this section aims to explain technical terms like "blinded", "placebo", "randomised", and "crossover" using non-technical language. Diagrams or figures are used to explain terms that are otherwise difficult to understand.

"This study compared pregabalin with placebo for the treatment of DPN. A "placebo" looks like a medicine but does not have any medicine in it. Comparing pregabalin to placebo helps researchers understand how well pregabalin works, and how safe it is. This study was done in 2 phases or parts: first a single-blind phase, and then a double-blind phase."

An explanation of "single-blind" and "double-blind" and a figure to help explain the two parts of the study are also included.

Third and fourth pages

The third and fourth pages of this lay summary (Figures 4 and 5) describe the study conduct, outcome assessments, and results using non-technical language.

What happened during this study?

This section briefly explains the treatment procedures, medications given, how they were administered, and what the patients were asked to do.

"In this phase, half the patients took pregabalin, and the other half took the placebo. All patients took 1 capsule 3 times each day… Doctors asked patients to keep a pain diary and rate their pain from 0 (no pain) to 10 (extreme pain) every day… Doctors reviewed these diaries during each clinic visit."

As with the study design, an illustration is used to help explain.

What were the study results?

This section gives details on the study results, for example, if the medication was effective, how many patients benefited from the treatment, and additional benefits of the treatment. Numerical data can be presented as tables or, as in this example, figures to help aid understanding.

The section starts with a bottom-line summary of the study findings:

"No, pregabalin did not relieve the pain of DPN any better than the placebo, which contained no medicine."

This section then details what happened in the different parts of the study, including how many patients were included in each study group and what happened to patients. A conclusion for each part of the study is also provided. Finally, the section concludes (on the fourth page) with information about any additional benefits of the treatment:

"Most patients who finished the study felt better than when they started. Patients had less trouble sleeping, and less anxiety and depression."

What side effects did patients have?

Apart from understanding whether the treatment was effective, patients and the public need to be confident that it was safe. Because their understanding of medical terminology is very limited, this section needs special care. As in other sections, numerical data can be presented in tables, as in this example, or as figures. The section begins with a general explanation of side effects:

"A side effect is any medical problem caused by a

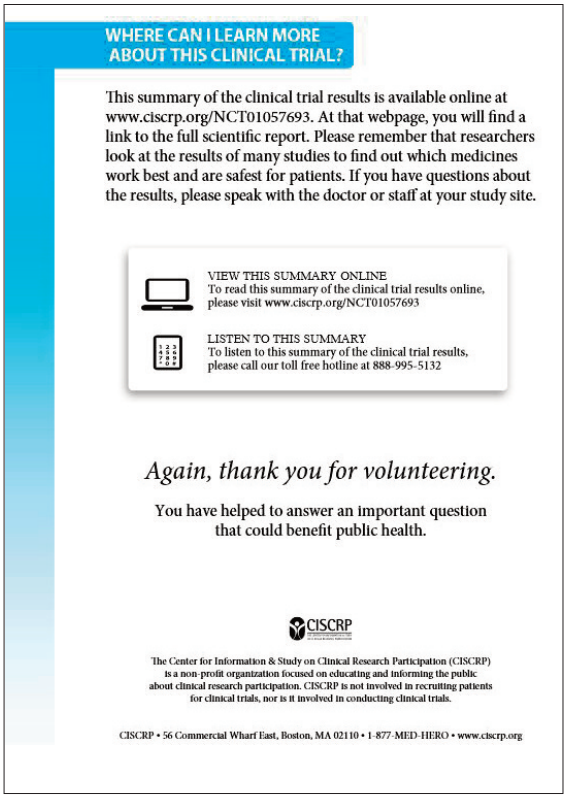


Figure 6. A typical lay summary: last page.
Source: Center for Information & Study on Clinical Research Participation. [12]

drug or treatment. A lot of research is needed to know whether a drug causes a medical problem. So, when new drugs are being studied, researchers keep track of all medical problems that patients have."

This is followed by the safety findings from the different parts of the study:

"In the single-blinded phase of the study, 331 out of 665 patients (50%) had a side effect after taking pregabalin, and 45 patients (7%) left the study because of a side effect. The most common side effects were: edema (tissue swelling), dizziness and sleepiness during the day."

Table 1: Examples of plain-language replacements for technical terms to use in lay summaries

Avoid using	Consider using
Hyperglycaemia	High blood sugar
Hypertension	High blood pressure
Leucocytes	Blood cells that fight infection
Angina	Chest pain
Metastasis	Spread of cancer
Adverse drug reaction	Side effect
Inflammation	Swelling

After that, serious side effects, including a general explanation, are described:

"A side effect is considered "serious" when it is life-threatening, causes lasting problems, or needs hospital care. Some patients in the study had serious side effects, but no patients died during the study."

Last page

Where can I learn more about this clinical trial?

This section informs patients and the general public about how to obtain further information about the study (Figure 6):

"This summary of the clinical trial results is available online at www.ciscrp.org/ NCT0 1057693. At that webpage, you will find a link to the full scientific report… If you have questions about the results, please speak with the doctor or staff at your study site."

The web address is also provided in a box at the bottom along with a phone number to listen to the lay summary.

Best practices for writing a lay summary

Audience

Keep in mind that the summary is meant for general public or study participants. This audience will not be familiar with medical terminology, so the lay summary needs to be written using non-technical terms. To avoid boring the reader, the lay summary must not be too long or too simple. This can be best achieved by having patients, members of the general public, or patient advocacy groups participate in preparation of lay summaries through user testing.[14,15]

Language

The text in a lay summary should be written for a grade 6–7 reading level. The study rationale should be explained in plain language and should provide background information about the disease and drug studied. Sentences should not be too long, and technical terms should be replaced by plain-language words or phrases (see Table 1). Of course, long sentences cannot always be avoided, for example, when explaining certain technical terms. In such cases, an illustration may help.

Active voice should be used to engage the reader and is most effective at communicating the information. Further, the text must not be too promotional to avoid misleading the reader. For example, saying that "drug X is effective in treatment" can be misleading because the summary is for a particular study, whereas the drug label is based on several studies. Another example is that although a phase 2 study might have provided promising results, they need to be confirmed in a phase 3 study, so great care should be taken when making statements about efficacy or safety. Finally, to ensure that the included patients and local public are informed, lay summaries should be translated into the language where the study was conducted.

Visual presentation

Lay summaries can include visuals to aid understanding and make the summaries more appealing. Although visuals such as infographics do not improve comprehension, they are more enjoyable and user-friendly.[16] To avoid misinterpretation, visuals should be simple and accompanied by text. The text itself can also be improved by using visual elements like headings, subheadings, bullet points, and sidebars.

Data presentation

Numerical data are always difficult to comprehend when presented as text. To improve comprehension and presentation, they can instead be provided in tables and figures.

Disclaimers

The most important concern for lay summaries is that the general public may misinterpret the results and draw conclusions that go beyond the limitations of the study. For example, it is inappropriate to conclude that a drug is beneficial based on the results of a single study. Thus, lay summaries should always be accompanied by disclaimers stating that results of a particular trial do not display the complete medical picture and that patients should always consult their doctor before changing their ongoing therapies.[17]

Conclusion

Making the results of clinical research available

to patients and the general public is critical for improving awareness and therefore health outcomes. Lay summaries accomplish this by providing the results in a plain language. The EU Clinical Trials Regulation, which will come into force in 2019, mandates the posting of lay summaries in the EU database. Thus, medical writers need to be aware now about the importance of and best practices for preparing lay summaries.

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Disclaimers

The opinions expressed in this article are the authors' own and not necessarily shared by EMWA or their employer.

Conflicts of interest

The authors disclose no conflict of interest.

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