Plain language summaries (PLS), also known as lay language summaries, are summaries of clinical trial results written in a format that is understandable by “laypersons”. They are required by the European Medicines Agency (EMA) through the EU clinical trials regulation 536/2014 (Article 37) in an effort to increase clinical trial results disclosure and transparency.  

The current guidelines recommend the inclusion of the target audience in the review of PLSs, but patient involvement at any stage is not currently mandated by the regulations. In this article, Vidhi Vashisht et al., beautifully explain their experience of involving patient panels in the production of PLSs, and describe the added benefits and insights they have gained by doing this.

I hope that you enjoy Vidhi’s article as much as I did.

Best,  
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The goal of a PLS is to make clinical trial results available to clinical trial participants, patients, and the general public in language that is easy to understand without compromising scientific integrity and accuracy. It is also required that the content be unbiased and non-promotional. As laid out in the 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, PLSs should be written at a proficiency level of 2 to 3, which roughly corresponds to a 6th to 8th grade reading level. Furthermore, careful consideration of the flow of information, document layout, and use of visuals to present clinical trial results can greatly increase the comprehension of complex information for
readers who are not familiar with the intricacies of clinical trials.

The EU-CTR guidelines also encourage the involvement of patients, patient representatives, advocates, and members of the public in the development and review of the summary to assess comprehension and the value of the information provided.

**Patient panel review of PLSs**

**Background**

As PLSs are written for the general public and patients, it is strongly recommended that a patient panel review be conducted to ensure that the summary is clear and understood by the target audience. This review is sometimes also referred to as user testing, readability testing, or patient advocacy review, and is recommended by the EU CTR guidelines.

This article describes our experience of feedback from patient panel reviews of our PLSs.

To conduct the PLS patient panel review, panelists are recruited in the country for which the master PLS is written. For instance, when writing US English PLSs, panelists are from the United States.

- The criteria for being on a PLS panel is to be: familiar with the medical condition for which the PLS is written, which can be as either a patient, caregiver, immediate family member, or close friend.
- enthusiastic about research, although a panelist does not need to know about current research or be able to understand complex scientific terminology.
- able to listen to others and express his or her own views during the discussion.

**Methods**

Potential patient panel reviewers are identified through online forums, patient advocacy groups, and other networks based on the medical condition described in the PLS. Once the panelists agree to be a part of the panel, a written confidentiality agreement and guidance document are provided with instructions on how to join the discussion. The panelists are informed that the purpose of the panel discussion is to gain feedback on the clarity and readability of the PLS and the intention is not to promote any drug.

Panel reviews are conducted in an interview-style format, using a structured, two-way discussion to get solicited and unsolicited feedback on the PLS. Panelists are asked to provide their opinion on aspects of the PLS that are of specific interest to the clinical review team. Panelists are also encouraged to provide general feedback on all sections of the PLS, especially if any part is not easy to understand. Panelists are also asked to explain the results in their own words to confirm that the intended message is

**Figure 1. First impressions matter**

A clinical trial to find out if study drug can improve the eyesight of participants with presbyopia.

**Figure 2. Visuals to explain scales**

Total Mayo Score (TMS)

- Stool frequency subscore
  - 0: No symptom
  - 3: Very severe symptoms
- Rectal bleeding subscore
  - 0: No symptom
  - 3: Very severe symptoms
- Endoscopy subscore
  - 0: No symptom
  - 3: Very severe symptoms
- Physician's global assessment
  - 0: No symptom
  - 3: Very severe symptoms

Total Mayo score

- 0: No symptom
- 12: Very severe symptoms

About this summary

This summary is written to share the results of this clinical trial with the public in simple language. It describes why the study was needed, how it was done, and the results.
clearly reflected in the PLS. After the panel, a collated feedback report is created by the PLS writer for the clinical review team. This includes recommendations on how panel feedback could be addressed. After the recommendations are discussed and agreed upon with the clinical review team, updates are made to the PLS.

**Learnings from patient panel discussions**

The patient panel feedback on the PLSs written by our team over the past 3 years has helped us to identify the following improvement areas for PLS readability and comprehension.

**First impressions matter**

The first page sets the tone to help readers understand what the PLS is about and what information they will get by reading it.

- Create a study title that is clear and informative, providing a simple description of the condition for which the PLS is written (Figure 1).
- Add an introduction that explains what the document contains and why it has been written (Figure 1).
- Add context: inform the reader that the PLS only shows the results of one clinical trial and that broad interpretations about efficacy and safety, as well as health decisions, should not be based on the contents of this one document.

**Be aware of jargon**

The EU-CTR guidance suggests that the PLS should be written in everyday language. This should be reflected throughout the document. Without testing the PLS with the intended audience, a writer can only assume that the PLS is understandable. Conducting patient panel reviews allows writers to identify what technical or specialised terms, or jargon, should be simplified.

- Panelists recommend that scientific terms be simplified, or defined, in a way that can be understood by a non-scientific audience. For example, replacing “safety assessments” with “health check-up”.
- When discussing technical scientific concepts, such as mechanism of action, it is helpful to define technical terms that may not be well known outside of the industry. For example, if the study drug impacts expression of a protein linked with the disease, or if a certain enzyme or protein is being measured by researchers because its levels reflect whether or not the study drug is effective, panelists recommend adding additional text to connect the dots for the reader on why certain measures are important and what they imply. Readers find this informative and helpful, rather than having the PLS simplified to the extent that the rationale behind the study and study assessments is unclear.

- To provide another example, biomarker assessments are also of interest to patients. However, because of the technical nature of such results, it is recommended that the meaning behind each assessment is clearly laid out in simple terms, so that readers can draw conclusions from the data themselves, instead of having it “told” to them.

**Data and patient reported outcome scales are understood better as visuals**

Visuals, whether in the form of diagrams, graphs, or infographics, have been shown to greatly support the understanding of complex data. Discussions during patient panels confirm that visuals are preferred over an “all text” format.

- Scales used to describe severity of symptoms, as well as categories of information, are better presented as images rather than text in a document for the public (Figure 2).
- Panelists also recommend reiterating if

*Figure 3. A simple visual for the study design*
higher or lower values on a graph correlate with positive or negative outcomes for the patients. Although this information could be pieced together based on the introduction and study design sections, making results and figures standalone components that can be easily interpreted by readers has been found to be crucial in improving readability.

- Panelists feel that consistently using the same colors for specific treatment groups throughout the PLS allows them to more easily connect the information presented in the study design with the efficacy and safety results.

It is important to note that there should be a careful balance between the use of relevant infographics that aid the understanding of important concepts and text in the PLS. If not chosen carefully, or if relied on too heavily, visuals can also lead to confusion for the reader as they are subject to interpretation.

Leverage the study design to increase transparency

Explaining the study design helps to provide context for the clinical trial results. The study design description and figure should be specific, allowing readers to easily understand what type of assessments were done, how the study drug was given, if there was an impact on other medication that was being taken, and what type of a time commitment was required. Discussion during patient panels suggests that readers are interested in details such as route of administration, impact on concomitant medication, and timelines of the various periods of a clinical trial. All of these factors can be incorporated into the study description and design of the PLS, an example of which is provided in Figure 3.

Don’t forget your audience

While writing PLSs, the considerations for the target audience should not be limited to layout and word choice. Keep in mind any customisation of the PLS that can be done to make the information easily accessible to the patient population based on the medical condition or therapeutic area for which it is being written.

- For studies related to eyesight loss, larger font should be used to make the PLS easier to read. If possible, an example image can be added to demonstrate what type of eyesight loss is experienced by someone with that condition (Figure 4).
- In studies with paediatric patients, additional infographics and images should be incorporated to explain the content of a PLS. More white space should be intentionally kept in the document, as children can be easily overwhelmed by paragraphs of text.
- Cultural, geographical, and individual experiences may impact how readers interpret or understand the information in a PLS. Additionally, rescue medication or standard-of-care drugs may be marketed by different names in different countries. For example, an inhaler as rescue medicine is known in different countries as “salbutamol” or “albuterol”, so both were included in a recently written PLS based on feedback from the patient panel.

Be respectful

Finally, panelists regularly highlight appreciation for language that is respectful of the patients. Therefore, it is strongly recommended that writers be mindful of the terminology used in the PLS, differentiating it from other documents that focus on the experimental nature of clinical trials.

- Use empowering language so that the study participants feel respected.
  ✓ Use the term “participants” instead of “patients” or “subjects”.
  ✓ Use the term “condition” instead of “disease”.
  ✓ Use “treatment did not benefit the participants” instead of “participants failed the treatment”.
- Be extra sensitive while writing PLSs about conditions that have associated social stigma, such as mental illness.
- A small component that is often appreciated by panelists while reading PLSs is the thank you note acknowledging the time and effort of participants without whom clinical trials would not be possible (Figure 5). This is also recommended by the EU-CTR guidelines.1

Conclusions

The feedback we have received from our patient panels agrees with recommendations by the EU-CTR guidelines and with health literacy principles. Nowadays, more than ever, there is a demand for transparency and engagement of patients in clinical trials. PLSs provide an avenue through which clinical trial results can be shared with the general public in a way that is both meaningful and easy to understand. However, since PLS writing is different from traditional medical and regulatory writing and has a different target audience, it is important to take into
account the perspectives and opinions of the public and patient population for whom these documents are being written. The best way to test the effectiveness of this document is by conducting patient panel reviews and soliciting feedback from people familiar with the medical condition for which the PLS is written.

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

Conflicts of interest
The authors declare no conflicts of interest.

References

Figure 5. Showing appreciation

Thank you to the study participants!

Thank you for taking part in this clinical study for Condition X. Your time and commitment has helped us move one step closer to bringing better treatments to patients.