

The ABCs of paediatric plain language summaries



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Abstract

Plain language summaries need to be written at a proficiency level of 2 to 3, which roughly corresponds to a 6th grade to 8th grade reading level. Writing these for paediatric audiences brings even greater challenges.

For communication to be effective, the needs of the target audience should be the foremost consideration. A document written for a child needs to be different from a document written for an adult reader.

In an attempt to understand preferences among the paediatric participants, the authors tested 3 different formats of plain language summaries with 30 paediatric volunteers. This article discusses insights gained from this exercise.

Plain language summary (PLS)

Plain language summaries (also called layperson summaries, lay summaries, lay language summaries, simple summaries, and trial results summaries) are summaries of the aggregate results of clinical trials written in plain language. They are required by the European Medicines Agency (EMA) through the EU Clinical Trials Regu-

lation 536/2014 (Article 37).¹ The main goal of writing a PLS is to help the study participants and the public understand clinical study results while keeping scientific integrity intact.

Writing a PLS for a paediatric audience

In general, PLSs need to be written at a proficiency level of 2 to 3, which roughly corresponds to a 6th grade to 8th grade reading level. Writing PLSs for a paediatric audience brings greater challenges.

For communication to be effective, the needs of the target audience should be the foremost consideration. A document written for a child needs to be different from a document written for an adult reader. While the specific requirements vary by age group, a document written for a child often has:

- Shorter sentences and simpler words
- More white spaces
- More graphics.

These are not just cosmetic aspects of a document, but fundamental requirements to help children understand the content and to hold their attention. Therefore, it is important to apply these principles while writing PLSs for children and/or adolescents.

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 use² mentions that sponsors of paediatric studies should consider developing a child-focused version of the PLS that may differ in terms of presentation and style (more illustrations or graphics) to assist children in understanding trial results, over and above what is required under the EU CT Regulation.

While considering the appropriate format, the sponsor must ensure that the information presented is non-promotional, non-misleading, and factually correct, while still being easy to understand.

Different PLS formats

To better understand the impact of format and graphics on the readability of a paediatric PLS, 3 different formats of a PLS on pollen allergy were created:

1. Standard PLS
2. Infographic version
3. Illustrated version

Standard PLS

The standard PLS was a basic version that met the minimum requirements of a PLS:

- Text was suitable for people with low to average levels of literacy.
- Simple words and sentence structure were used.

- Basic graphics, e.g., diagrams explaining the study design, simple bar graphs for the primary endpoint results were used.
- Simple tables were used to report the safety results.

Figure 1 includes examples of the key components of the paediatric PLS. The full PLS for study CIGE025F1301 can be found at www.novartisclinicaltrials.com.³

Infographic PLS

The infographic PLS used a combination of text, icons, and charts to improve the readability and presentation of the document for a paediatric audience:

- All the readability elements of the standard PLS, described above, were retained in this version.
- Where possible, relevant icons or infographics were added to support the text, shortening the paragraphs of information. This also helped to add more white space in the document:
- A glossary of terms was included at the beginning of the PLS to familiarise the reader with the scientific terms used in the PLS.
- Previous testing suggested that bar graphs for primary endpoint results are easy to comprehend and thus were retained in this version.
- The tables to explain the safety results were changed into an infographic format.

These are not just cosmetic aspects of a document, but fundamental requirements to help children understand the content and to hold their attention.

Figure 2 shows examples of key differences from the standard PLS. The full infographic PLS for study CIGE025F1301 can be found at www.novartisclinicaltrials.com.³

Illustrated PLS

An illustrated version was created using the standard PLS as the starting point. The simple graphics and tables of the standard version were replaced with comic-style graphics. The text of the PLS was edited to make it more concise, so as not to overwhelm the children and adolescents.

Figure 3 shows examples of key differences from the standard and illustrated PLS.

Feedback from user testing on the 3 PLS formats

Children between the ages of 9 and 16 were asked to provide feedback on all 3 versions of the anonymised PLS. The children were asked to read the PLSs and provide their feedback either face-to-face or online. Their feedback was

Why was the research needed?

1 Researchers are looking for a better way to treat severe Japanese cedar pollinosis that is not completely controlled by the currently available treatments. Japanese cedar pollinosis is a type of seasonal allergy caused by Japanese cedar pollen. This allergy affects around 30% of the people living in Japan. A majority of the people affected have severe symptoms that impact their daily activities. Symptoms include sneezing, runny nose, stuffy nose, and itchy and watery eyes. Even with the available treatments, some patients still report symptoms during the cedar pollen season.

2 Most Common Non-Serious Adverse Events

	Drug X	Placebo
Total number of participants	161	175
Total participants affected with the most common events	16% (26)	12% (21)
Common cold	9% (15)	5% (8)
Sore throat	4% (7)	3% (5)
Flu	3% (4)	5% (8)

Figure 1. Examples from the standard PLS format



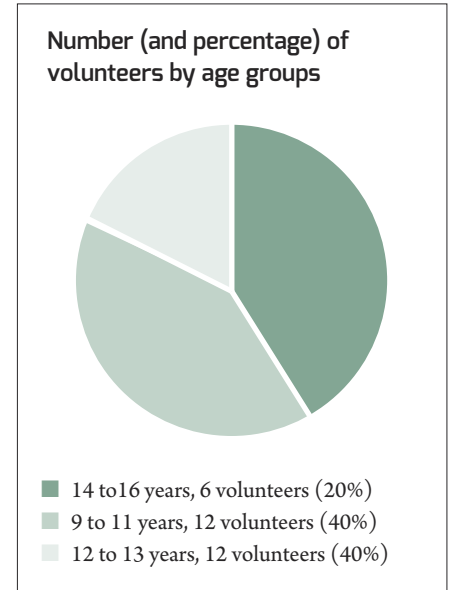
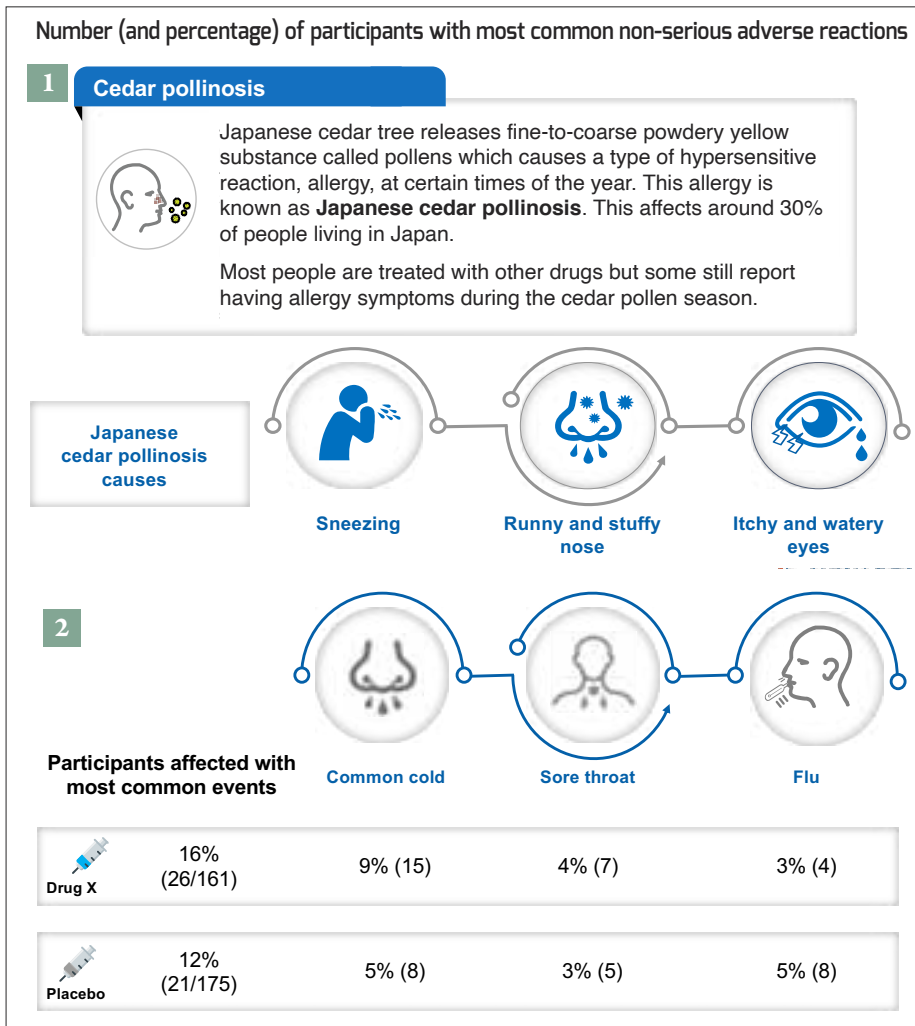


Figure 4. Number of volunteers by age group

Figure 2. Examples from the infographic PLS

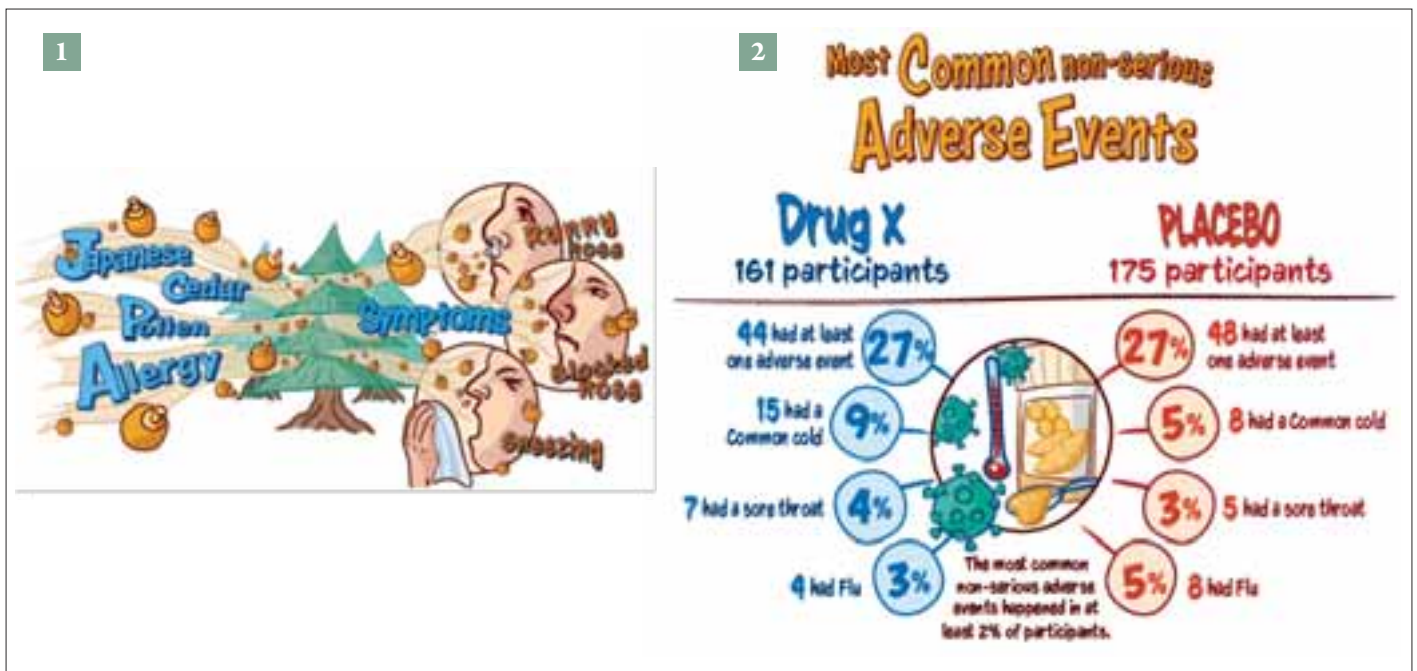


Figure 3. Examples from the illustrated version

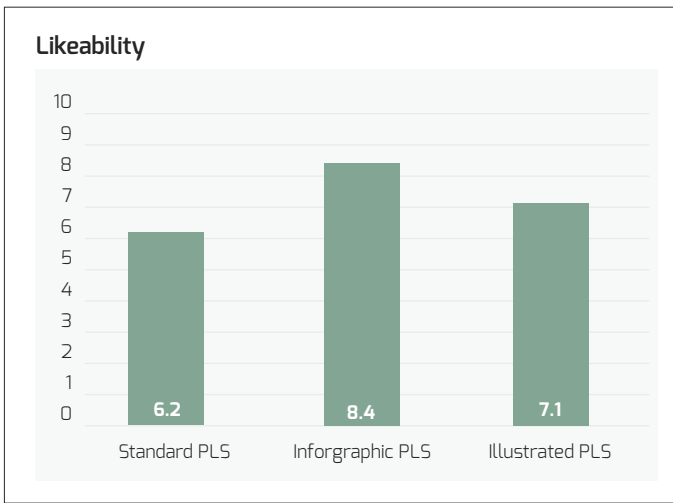


Figure 5. Likeability by PLS format

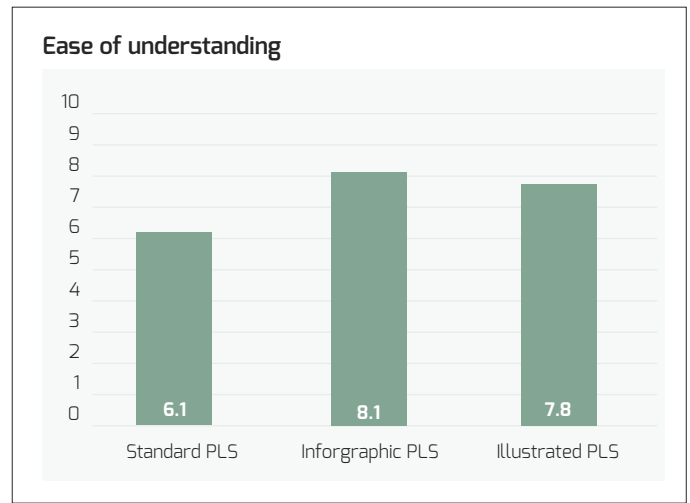


Figure 6. Ease of understanding by PLS format

recorded and analysed to identify preferences and trends.

Thirty volunteers (15 male, 15 female) between the ages of 9 and 16 provided feedback on the 3 PLS versions. Figure 4 shows the distribution of volunteers by age group.

The volunteers were from 3 countries: two in the US, 12 in India, and 16 in the UK.

Likeability of the PLS based on format

All volunteers were asked to rate the likeability of each PLS format on a scale of 1 to 10.

How much do you like the summary? Rate it on a scale of 1 (don't like it at all) to 10 (it is perfect).

The infographic and illustrated versions were preferred over the standard version. The average scores for likeability are presented in Figure 5.

When asked which of the versions was their favourite, 19 (63%) volunteers chose the infographic version, 7 (23%) volunteers chose the illustrated version, and 4 (14%) volunteers chose the standard version. The preference for a particular version did not differ based on the volunteers' age. The majority of volunteers (including the ones who were between 14 and 16 years old), acknowledged that the illustrated PLS was engaging and appropriate for their age group.

The main reasons shared by volunteers for preferring the infographic and illustrated versions over the standard format were:

- Inclusion of relatable and meaningful graphics
- Good balance of text and graphics
- More white spaces

When asked what they would like to change in the infographic version, which was the most liked, 4 volunteers recommended using more colours than just blue and black.

Ease of understanding

Volunteers were asked to rate their ease of understanding of each format of the PLS on a scale of 1 to 10.

How easy is it to understand the summary? Rate it on a scale of 1 (too difficult) to 10 (really easy to understand).

According to the volunteers, the infographic and illustrated versions were easier to understand than the standard version. The average scores for ease of understanding are presented in Figure 6.

The main factors that seemed to help volunteers understand the PLS were:

- Appropriate graphics that increase comprehension
- More white spaces between different sections
- A glossary of terms at the start of the summary (specific to infographic version)

Length of the document

The length of a PLS is believed to be an important factor related to the readability of the document. More so, for a paediatric PLS considering the shorter attention span of children. Table 1 presents the number of pages in each of the PLS formats tested.

When asked about the length of the document, 12 (40%) volunteers commented that the PLS should not be too long, as otherwise,

Table 1. PLS Page Length

PLS Format	Pages
Standard PLS	8
Infographic PLS	12
Illustrated PLS	8

they could lose interest. All of these participants were between the ages of 10 to 14 years. Fourteen (47%) volunteers said that the length did not matter to them as long as the PLSs are easy to understand.

Interestingly, 13 (43%) of the volunteers felt that comparatively, the standard version was too long and boring. Considering that the standard and illustrated versions were of the same length and the infographic version was even longer, this finding indicated that the use of white spaces, use of graphics, and format of the PLS influenced the perceived length of the PLS. This suggests that design and layout of the document are more important than the length of the PLS for these readers.

While sponsors should be cautious not to write very lengthy PLSs, they should not compromise on including the graphics and white spaces just to remain within a certain page limit.

Trust towards the sponsor

When asked whether they trust the sponsor of the clinical trial based on the PLSs they have read, all volunteers confirmed that they trusted the sponsor.



When asked if their feelings towards the sponsor changed based on the format of the PLS, 19 (63%) responded that the format did not change their trust and feelings towards the sponsor. For the remaining volunteers, 8 (27%) felt most trust reading the format they liked the most, which showed that their trust was directly linked with their preference for the PLS format.

This suggested that readers' feelings of trust towards the sponsor are dependent on multiple factors, including ease of understanding of the document and perceived reliability of findings, and may not be directly influenced by the format.

Conclusions

While creating PLSs for paediatric audiences, sponsors should not restrict themselves to a single template and should tailor the PLS content by:

- Applying the fundamental communication

strategies for the different age groups within the paediatric audience

- Creating a good balance between text and engaging graphics
- Providing tools like a glossary at the beginning of the PLS.

Sponsors should consider incorporating user testing in the PLS writing process, especially for paediatric PLSs. This will allow sponsors to develop a stronger understanding of their audience to create better PLSs.

Acknowledgements

A special thanks to Stuart Donald, of Kinapse, a Syneos Health® company, for his guidance and advice on this article.

Disclaimers

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

Conflicts of interest

The authors declare no conflicts of interest.

Data availability statement

For inquiries about data and other supplemental information, please contact the corresponding author.

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