

Creation of a patient-centric patient lay summary in the local language

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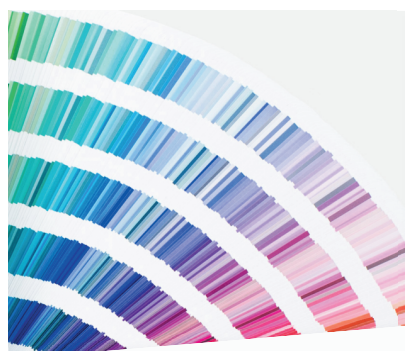
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Abstract

Prior to this project, no patient lay summary (PLS) had ever been developed locally in Japan. In order to create a PLS that is more tailored to local patients, we attempted to develop one in and for Japanese. Such PLS was drafted based on the disclosed summary of the clinical study report. We took a composite approach in refining the PLS by researching on lay language and patient-friendly designs. At the same time, we ensured scientific accuracy through consultation with experts such as physicians and statisticians, practised diligence on regulatory and legal aspects, and incorporated patient's voice by consulting a local patient advocacy group. We successfully created a PLS in the Japanese language for the first time, which was more patient centric than those translated from another language.

While summary results of clinical trials have commonly been posted on global websites such as clinicaltrials.gov¹ and EU Clinical Trials Register,² the European Union Clinical Trial Regulation No. 536/2014³ states that sharing clinical trial results to study participants in the form of a lay language summary is also an important endeavour. In Japan so far, we have distributed patient lay summaries (PLSs) for two clinical trials,⁴ which were originally written in



この治験の経緯

日本で実施したこの治験には、25の医療機関から122名の患者さんが参加されました。当社は、この治験のデータをもとに、この薬の働きに関する結果報告書を作成しました。この「治験結果のまとめ」はその結果報告書をわかりやすくまとめたものです。

ご協力、ありがとうございました！

このたびは、治験にご参加くださり誠にありがとうございました。この治験は2009年5月に開始し、2014年12月に終了しました。あなたを含む100名の患者さんにご参加いただき、疾患に対するこの薬の働きを調べました。この治験の実施を依頼した当社は、この治験にご参加・ご協力して下さったみなさまに治験の結果をお知らせすることは、とても重要であると考えており、この「治験結果のまとめ」を作成しました。このまとめをお読みいただくことで、みなさまが新しい治療法の開発に貢献されていることを知っていただければ幸いです。



English and translated into Japanese by an external organisation. In order to create PLSs that are more tailored to local patients, we have pioneered creating a Japanese PLS starting from scratch.

We formed two teams: One was responsible for researching on the characteristics of lay language, developing a template, communicating with a patient group, and considering legal and regulatory aspects; the other took charge of drafting a PLS. The two teams collaborated in refining the PLS and developing a process of PLS preparation. The team members voluntarily participated in the project and were consisted of medical writers and members of the document management group.

Developing the template

To develop a patient-friendly template, we first gathered patient information materials at local hospitals and clinics and critically evaluated their designs concerning legibility and readability. We also looked for relevant guidelines and design principles. We adopted the concept of “universal design” for effective communication⁵ and in particular considered the following aspects:

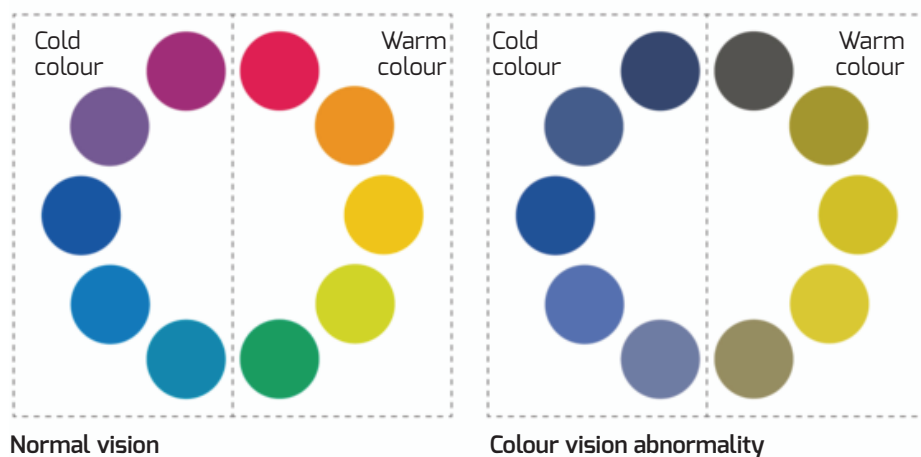
- Font and style of text: We

chose to use a recommended Japanese font Meiryo primarily, as it has a very clear typeface that maintains high legibility even in bold style. Also to enhance legibility, we used a font size larger than what we would normally use for regulatory documents (i.e., 12-point size was used for the main text of the PLS while 10.5-point size would normally be used for regulatory documents).

- Line spacing: Wider line spacing was used to optimise legibility and readability. This also allowed us to place a Japanese reading aid (in form of syllabic scripts) above some Kanji characters, which are similar to Chinese characters, in order to show how this text should be read. This was a part of the attempt to keep the language level equivalent to a Japanese junior high school graduate.
- Colours: In particular, a barrier-free colour scheme (see Figure 1) was studied to make sure that even patients with colour vision abnormality can appreciate the PLS without difficulty. People with colour vision abnormality have difficulty differentiating among cold colours or warm colours. For instance, it is hard for them to distinguish between red and green, purple and blue, or orange and yellow.

We adopted the concept of “universal design” for effective communication.

Figure 1. A colour scheme comparing how people with normal vision and with colour vision abnormality perceive cold and warm colours based on Takahashi and Katayama.⁵ (Reprinted with permission)



- Page layout of text sections: Text headings and special messages such as “thank you” should be easily discernible. This also allows readers to easily navigate through the PLS.

Although the primary purpose of distributing a PLS to patients is to share clinical trial results, it also provides pharmaceutical companies the opportunity to convey their appreciation of patient participation in a study.

Aside from the points suggested by the universal design concept, we believed that the appearance of the overall printed form of a PLS was also important as it is intended for persons in already stressful situations. For instance, an accompanying image in a text can appeal to viewer’s senses and stir positive emotions, which

can consequently alleviate the stress associated with illness. In this case, we chose the image of dandelions (Figure 2) because it is not only a flower familiar to many, it also has a bright colour and is very resilient. It has been used as a symbol of courage in many cultures and could represent clinical trials spreading “seeds” of possibilities. Further, we made sure that the picture followed a barrier-free colour scheme (i.e., predominantly blue and yellow), and did not use brand colour or image so that it could be applied to any drug in Pfizer.

We also identified standard texts (e.g., “thank you” message, headings for an introduction, background, etc.) for the PLS and inserted them in the template as default texts. Moreover, we

Figure 2. Picture used in our patient lay summary.

(Japanese text translation: “Dandelions spread their seeds when the wind blows. Clinical trials spread seeds of possibilities for a healthier world through your cooperation.”)



風に種を乗せて多くの花を咲かせるタンポポ ——
治験は皆様一人ひとりのご協力により、
より健康な世界への「可能性の種」を広げています。

followed the advice of our legal department, in which we incorporated the following information into the template:

- The date of document creation at the end of the template to control document versions and prevent any post-approval revisions; and
- A cautionary statement requesting patients to refrain from posting on social networking service, etc.

Drafting

We drafted the PLS based on the Public Disclosure Synopsis as posted on the Pfizer website.⁶ As reference for Japanese lay language, we used informed consent documents (ICDs). A comparison of the drafting process between the previous and our current model is shown in Figure 3. In our current model, no external organisation was involved (i.e., solely authored by Pfizer Japan). Aside from paying particular attention to the above mentioned aspects of design, language and structure, and not being promotional, the draft was reviewed by in-house experts (e.g., physicians, statisticians, legal and regulatory experts) and principal investigators to ensure scientific accuracy and suitability for public disclosure. It is important to mention that we also sought feedback from a patient advocacy group that had no direct involvement with the clinical trial.

Finally, we used the following checklist of questions to ensure that the PLS was patient friendly in both format and content:

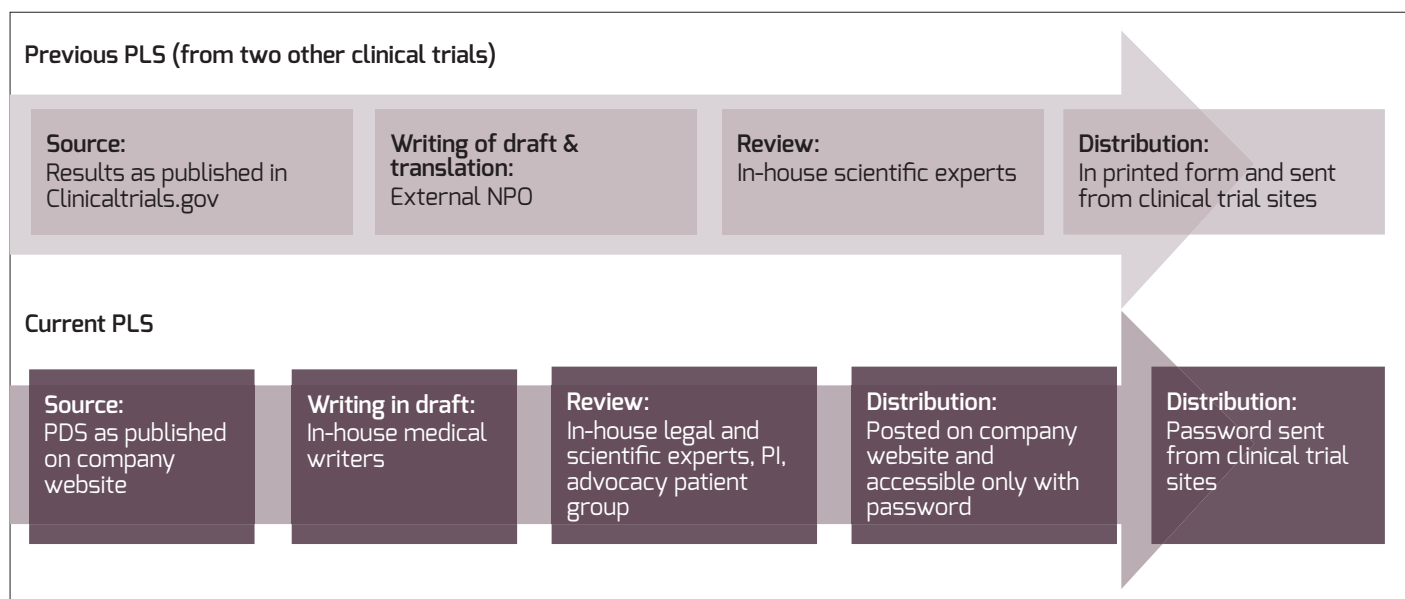
- ✓ Is it easy to understand?
- ✓ Is the language level of the content equivalent to that expected from a Japanese junior high school graduate?
- ✓ Are there arbitrary statements?
- ✓ Are there any inappropriate words?
- ✓ Can patients understand accompanying charts effectively?
- ✓ Is the text length appropriate?
- ✓ Are the font size and colour scheme appropriate?
- ✓ Are illustrations appropriate?

Delivery to patients

The PLS was posted on the Pfizer Japan’s website⁷ in PDF format and protected by a password. The link and the password were provided to the study participants at clinical trial sites.

Figure 3. Two different processes of creating a PLS in Japan

(PLS= patient lay summary; NPO= non-profit organisation; PDS= Public Disclosure Synopsis; PI= principal investigator)



Feedback from a patient advocacy group

Overall feedback was favourable and are summarised as follows:

- Easy to read
- Very polite writing and well organised (starting with the “thank you” message, then moving on to the background of the trial, the rationale for research, the method, and the results)
- Generally, easy to understand due to the explanations provided before or after technical terms such as placebo and adverse event
- Warm and soft image of the dandelion suited to alleviate patients’ pains due to illness

With these comments, it appeared that the locally developed PLS was more patient centric in language, content, and design. Using the local language from the drafting stage additionally made it easier to create a PLS that is more culturally and ethnically appropriate and thus suited the sentiment of local patients.

The previous lay summaries of the two other clinical trials, which were translated from English, were highly appreciated by patients at clinical study sites,⁴ as there had been no other attempt to provide patient access to clinical trial results. The PLS directly created in Japan received more favourable feedback because it did not only provide information but also presented the information better. In this way, the impact of PLS on patients was stronger.

We believe that enhancing patient literacy on drug development would help advance patient centricity in the pharmaceutical industry. Distributing the PLS would serve as a great opportunity to educate patients about clinical trials, helping us form a win-win relationship in drug development. In addition to giving patients access to the clinical trial results, further involvement of patient advocacy groups in preparing clinical trial related documents such as ICDs would also contribute to foster a culture of trust between pharmaceutical companies and patients. Increased transparency as regards clinical trials and their outcomes would allow us to conduct clinical trials more effectively and ultimately lead to the acceleration of drug development.

Recommendations

Because the PLS is not a regulatory document (e.g., clinical study report) and is intended for patients, we need to be particularly careful in stating conflicts of interest and in refraining from being promotional in both content and tone. Indeed, as more steps were required to ensure the non-promotionality of a PLS, it took a longer time to finalise the PLS than any regulatory document.

To prepare a PLS more efficiently in the future, we identified a few areas that need to be improved or explored:

- Establishment of an effective way to confirm that the PLS is not violating the promotion code

- Ensuring compliance with local regulations and practices
- Assessment of medical and statistical appropriateness in paraphrasing technical content in lay language
- Finding an effective way to involve principal investigators
- Establishing a good relationship with patient advocacy groups in Japan
- Increasing patient involvement in preparing the ICDs to promote patient centricity
- Collaboration with regulators to establish a framework for clinical trial results disclosure in the industry
- Improvement of medical writing skills in lay language/ local language

We believe that industry-wide efforts are necessary to achieve these points effectively.

Conclusions

We successfully created a PLS in the Japanese language for the first time. The locally developed PLS was more patient centric than those translated from other languages, allowing us to communicate clinical trial results in a more patient-friendly manner and helping us to form a better relationship with patients. Using the patients’ local language and being culturally sensitive are one of the most patient centric activities pharmaceutical companies can undertake.

We hope that our current attempt in developing a PLS locally would help trigger an

increase in the distribution of such summaries in Japan. We believe that locally developed summaries would bring more benefits to both patients and the pharmaceutical industry, especially in more culturally and linguistically diverse regions such as the EU.

Conflicts of interest and disclaimers

The authors are employed by Pfizer Japan Inc.

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Mina Izuchi is a member of the Medical Writing Group at Pfizer Japan. She has over 10 years of experience as a regulatory writer mainly in the area of vaccines. She led the construction of the website for posting the patient lay summary.

Fumiharu Naganeo is a member of the Document Management Group at Pfizer Japan. After 4 years of medical writing experience, he now collaborates with medical writers as a regulatory dossier coordinator. He is an expert on eCTD submission and the subsequent disclosure.

Junko Tanabe has over 10 years of experience in regulatory editing and document management. Being an expert on “submission-ready” documents, she has a strong interest in “universal” document design for providing information in a patient-friendly manner.

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Chikara Kikuchi has more than 20 years of experience in regulatory affairs and is currently the Senior Director, Regulatory Affairs, at Pfizer Japan and Vice-Chair of the Drug Evaluation Committee in the Japan Pharmaceutical Manufacturers Association.