Regulatory Matters

SECTION EDITOR

Jennifer Clemens, ELS
jennifer.clemens@merck.com

Writing clinical trial summaries in plain language: Some tips from patient education

Ever since the EMA mandate for plain-language summaries of clinical trials was codified in Clinical Trial Regulation EU No. 536/2014, medical writers have grappled with the task of making these documents accessible to the public, including to participants with low literacy.

Although the regulation is not fully applicable pending approval of the planned portal for clinical trials information,[1] a great deal of effort already goes into creating clinical trial summaries (CTS), as they will be called here. The European Union's guidance document refers to them by four different terms: "summary results", "lay-person summaries", "lay summaries", and "clinical trial results for laypersons" in its first three paragraphs.[2] The word "lay" is avoided here partly because of its frequent use in ecclesiastical circles, among other reasons.

The effort expended to develop CTS is partly because the EU 536/2014 implementation has been pushed back so many times, giving us ample time to prepare, practice, and prepare again to explain trial results to the public.

The challenge of writing plain-language summaries

Experts have already described the challenges of creating CTS.[3-5] The EU's guidance document on creating CTS lists elements that must be included and provides a template.[2] However, the format, language level, and design of summaries vary across organisations that produce them. This gives sponsors, writers, and designers both freedom and room for uncertainty.

In addition, most writers who are tasked with creating CTS work in the regulatory space. They are trained and accustomed to creating complex, data-rich documents for audiences with high general literacy, high health and science literacy, and a strong interest in the data and results. These readers are nearly the opposite of most members of the public.

An outsider's perspective

I first wrote CTS in early 2015, working with the nonprofit Center for Information and Study on Clinical Research Participation (CISCRP). My background is in writing instruction and patient-care administration – far from the laboratory bench, but closer to patients and families.

As the demand for plain-language CTS grew, more writers were needed. Specialists in patient education make up a small fraction of medical writers in the United States, and as the regulatory environment already had many writers available, it seemed logical for them to take over most CTS work.

The solution seems natural, but the differences in perspective between scientists and non-scientists, and in the perception of what makes for accessible writing, present some hurdles. In this article, I share a few of the challenges I believe regulatory writers cope with and offer some suggestions from the other side of the bench.

A glimpse through patients' eyes

A few years ago, my uncle Brian was diagnosed with double-hit lymphoma. The prognosis was poor, and a stem-cell transplant trial was his best chance of survival.

A highly educated member of the US diplomatic corps, my uncle spoke and read several languages. He was an accomplished amateur photographer with a passion for aviation, and a world traveller with five grown children. He and my aunt were not concerned with how they could advance clinical research. They were focused on my uncle's "new birthday" – the January 1 transplant date. As his son-in-law said at the funeral, "He wanted to live."

The world of medical research was not one they chose to enter. Had my uncle lived to receive a CTS, he would likely have skimmed it, tossed it on his desk, and returned to work.

Keep our excitement, remember their perspective

Research is the lifeblood of an academic career. Original contributions and the discovery of new knowledge bring us rewards ranging from tenure to outright fame. The desire to ameliorate suffering and improve public health also figure in.

Writers who create CTS are likely excited

about the clinical research enterprise, and we know that participants want to learn the results of their trials.[6] But it's important to remember that their main interests lie elsewhere. I once heard an interviewer ask a trial participant, "Why did you decide to join the Keytruda [pembrolizumab] trial?"

"I was 40 years old, I've got kids, and I had lung cancer. I would have tried anything," he said. "I'm just lucky it's working for me."

The curse of a specialised vocabulary

If you've worked in science, medicine, or nursing for many years, its specialised language, or jargon,[7] is the water in which you swim. Using short, familiar words is a key tenet of writing for the public, but it's easy to forget that "lab", "exam", "follow-up", and "outcome" are more familiar to health care providers than the public.

But while readers may put up with some jargon in a medical thriller, CTS readers may simply give up. I tutor lower-literacy adult learners who typically skip unfamiliar words or read them aloud as nonsense syllables. I have learned first-hand that reading a document is not the same as understanding it.

Table 1 provides a few examples of more jargon terms to avoid, with plain-language translations. Note that plain language sometimes involves using more words to translate scientific and medical terms into everyday language. Jargon is a form of shorthand within the community, allowing us to communicate quickly with each other. Those outside the community simply need different words.

The US Centers for Disease Control offers a variety of plain-language resources,[8] and many glossaries are available. Avoid the mistake of just translating in a way that feels right to you because you are steeped in scientific vocabulary. When writing for people outside this environment, your fluency is actually a disadvantage. You can learn more about plain language and readability in *Medical Writing*[9] and elsewhere.

The challenge of writing simply

The following sentence is from the first page of a CTS written in "plain language."

This clinical study for the drug nusinersen, also known as ISIS 396433, helped researchers learn more about the safety of nusinersen and if it might help infants with spinal muscular atrophy, or SMA.

Health literacy expert Helen Osborne and others recommend a single main idea and a maximum of about 15 words in each sentence.[10] Other readability guidelines recommend eight to 11 words, particularly for content that is read online.[11] The sentence above is 33 words long and contains several ideas:

- **The study drug is called nusinersen.** Readers other than experts will probably skip the drug name, or read it as nonsense syllables.
- **The drug has another name**, likely also skipped or read as nonsense syllables. (Ask five non-scientists to read "ISIS 396433" and "nusinersen" in the sentence and observe their strategies for handling these technical terms.)
- **The study helped researchers learn something.**
- **The drug is intended for infants** [a medical term] with a certain condition [medical term, medical abbreviation].

Microsoft Word's readability checker uses the Flesch-Kincaid reading level. The validity and usefulness of readability formulas has been extensively discussed,[12] but the MS Word checker is readily available. By this measure, the sentence above reads at Grade 18.7.

> The EMWA and AMWA directories can help you find plain-language and patient education specialists.

Specific techniques and training are essential to write plain-language content. The syntax of the sentence above has not been modified for the general reader, and only some of the words are modified to plain language. Here is a sample plain-language translation:

Your study was about a medicine called "nusinersen" (say "NEW-suh-NER-sen"). Scientists wanted to learn more about how safe it is. They also wanted to know if it helped babies with a problem called "spinal muscular atrophy" (say "spy-null MUSS-kew-lur AT-row-fee"). You might also hear this problem called SMA (say "ess-em-AY").

Reading level? Grade 8.4, according to the MS Word readability checker. There are 12.5 words per sentence. Not perfect, but more accessible for general readers. A skilled plain-language editor can adjust the reading level further to accommodate readers at different levels, including children.

The Medical Library Association has developed MedSpeak,[13] a resource to help patients and other members of the public understand medical and scientific terms. Many other resources are available for medical writers and editors to use in creating clinical trial summaries. You can find MedSpeak at https://www.mlanet.org/p/cm/ld/fid=580.

Creating accessible content is not just about word choice, but about arranging ideas in an order that the readers can easily follow, helping them access medical terms that must be included, and making the container for ideas, the sentence, easier to open.

What to do (for now)?

Researchers, writers, and editors have long worked in teams – flexible and customised for specific projects. Our profession is also dedicated to continuing education. We can build on these strengths to do the following.

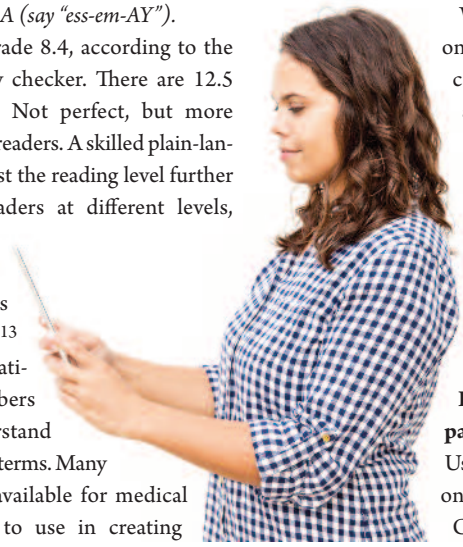
Train regulatory writers in plain language

The Plain English Campaign in the UK, Simply Put guide from the US Centers for Disease Control, and organisations such as Health Literacy Media and the Maximus Center for Health Literacy provide guidance and training in writing plainly for the public, as does the Plain Language Association International (PLAIN). Writers interested in writing CTS for participants will ideally pursue training from these sources and others.

Plain-language and health literacy training for regulatory writers, sponsored by employers including contract research organisations, would allow companies to use their current teams to produce truly accessible documents that meet the spirit of EU No. 536/2014.

Use specialist editors as needed

Patient education (full disclosure: my specialty) is a small sub-field of medical communications. It requires a different set of techniques and aptitudes than writing regulatory documents, as well as familiarity with principles of health literacy, readability, and usability.



With a plain-language editor on the team, a regulatory writer can produce a CTS first draft and have it edited for readability, ensuring that both the science and the accessibility are top-notch. The EMWA and AMWA directories can help you find plain-language and patient education specialists.

Include truly naïve participants in reviews

Using "professional patients" is one of the major confounds in CTS user review. By profes-

sional patients, I mean dedicated patient advocates or activists who are highly familiar with a given condition and the associated terminology.

If a CTS review group includes a physician, a social worker, a participant who serves as a patient advocate, and two randomly chosen participants, this is not a review group of five, but more likely of two. The physician, social worker, and patient advocate have too much expertise to provide the general public's perspective.

Why we do it

Aside from the EU regulation, creating plain-language summaries of clinical trials is part of a much larger trend towards patients taking part in their own healthcare. Thus, adjusting our perspective to match participants', seeking training and assistance from plain-language specialists, and including naïve participants in our reviews is not simply the appropriate move for our times. In the current climate of fear around COVID-19 and the struggle for greater equity worldwide, striving to increase participants' access and comfort level with research information represents genuine scientific progress.

Table 1. Ten to translate: Medical or science jargon with suggested plain-language translations

Here are some terms that seem easy to understand if you have a scientific background or work in healthcare, but which are not common in everyday language.

Medical or scientific jargon	Plain-language translation
Adverse event	Medical problem
Biopsy	Sample; small sample for testing
Blood sugar	Level of sugar in your blood (not "blood glucose," because glucose is a scientific term)
Chronic	Long-lasting; keeps coming back; lasts more than 3 months
Diagnosis, diagnosed	Your condition (for "your diagnosis"); Learn if you have (for "to diagnose"); You have (for "to be diagnosed with")
Exam	Examination
Outcome	Result
Randomised	A computer assigns you to a group; put in a group by a computer
Screening, screening test	Check-up; to look for (for "screening"); Test to learn if you have (for "screening test")
Therapy	Treatment

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Genevieve J. Long, PhD
Independent medical communicator specialising in patient- and public-facing materials in plain language
glong@genevievelong.com