Clinical Trials Materials: Getting the Basics Right

How can we make sure that patients entering clinical trials know what they are signing up for?

There are legal as well as ethical obligations to ensure that a medical treatment, whether established or experimental, is only given to a patient with their informed consent. The right to self-determination has been the cornerstone of medical research since the Declaration of Helsinki was adopted over fifty years ago, yet a 2015 meta-analysis found that around a quarter of clinical trial participants over the previous three decades did not understand various components of their trial.[1] If this is the case, can we really consider their consent 'informed'?

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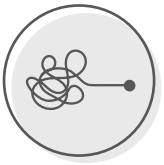
There are good reasons for patients' confusion. Clinical trial information is inherently complex and features that are second nature to those of us in the life science industry — placebo controls and double blinding, for example — can be bewildering to everyone else. The quantity of information surrounding each trial is also vast; details come at the patient thick and fast, each more puzzling than the last.

Moreover, patients who are eligible to enter a clinical trial may not be in a good frame of mind for absorbing new information. Depending on the study population, new recruits may be in pain, fatigued, nauseated or otherwise unable to give their full attention to a difficult conversation with their doctor. They may also feel anxious and intimidated by the 'untested' nature of the treatment. All things considered, it is no surprise that patients can find themselves overwhelmed.

There is not much to be done about some of these problems, but we can certainly address others through the careful design of patients' clinical trial materials. We at Cuttsy+Cuttsy have long advocated the use of plain English, visual cues and simple health literacy principles to help patients better understand the ins and outs of their trials.[2] We put this into practice with everything we create, and we are always looking for inspiration from the world around us to help us improve. In this paper, our Scientific Team Leader, Dr Liz Walder, and Senior Graphic Designer, Sarah Gracey, share some of the things we have learned along the way.



Keep things simple

Understanding the intended audience is key to any effective piece of writing, and with materials for patients it is important to keep messages as simple as possible. A 2015 study found 43% of patients struggled with text-only health information, and 61% had difficulties with mixed written and numerical materials.[3]

> "There's a high proportion of people within the UK that have problems with health literacy... people usually try to develop patient materials for reading ages between 10 and 14 years."
>
> Liz Walder

Avoiding jargon and using plain English is essential. While you may be familiar with certain words, patients may misinterpret them in ways you do not expect. Liz gives an example, when reading a book, a patient thought that a stool sample meant some kind of chair. "These sorts of words obviously aren't as obvious to patients as they are to me," she says. Liz also warns against letting scientific language creep back into otherwise patient-friendly writing. Not only can these be misinterpreted, but some can also be off-putting or even frightening for patients, such as the word 'toxicity'. Adding a glossary at the end of the document is a good way to deal with technical words that cannot be changed, and helps to make sure that the reader understands the terms as you were using them.

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Make the pages flow

It is easier to understand and remember things that fit together in a logical way, especially if they make a story. The order in which you present information has a large influence on how much of it your reader will absorb, and you should be careful to start broad and build details on top.

The layout of the document also influences comprehension. It must be obvious to the reader in which order they should read each block of text — something that can be unclear, especially in folded documents. To work out the most effective arrangement for the information flow, Sarah recommends printing the copy, tearing it up and then experimenting by moving the blocks around.

Draw out the important information

For those who think visually or do not absorb best from reading, diagrams and icons can make a real difference and are particularly useful for explaining complex ideas and communicating the most important messages. Our writers will often draft the first version, just to make sure that all the information is being conveyed, and then they will work closely with the graphic designers to make the diagrams clearer and more visually appealing. One aspect to consider is the white space on the page: it helps to prevent the information from being overwhelming and it can also direct the reader's attention around the page.

Be curious about your audience

Some of our work involves writing materials that will be translated into multiple languages. Appreciation of other cultures is needed; some colours, for example, have symbolic meanings to some audiences that we may not intend to convey.

Think practically

Really great clinical trials materials fit seamlessly into their environments, so thinking about where and how they will be used is a crucial part of the design process.

> "If you're making something for use in a lab or a potentially wet clinical space, printing it on normal paper won't be the best idea... In these cases, we print on synthetic material that can be wiped down."
>
> Sarah Gracey

"We also consider producing pocket-sized materials if they are likely to be carried around all day," Liz adds.

Sarah also advises considering information that needs to be permanently on hand. "If the audience needs to refer regularly to certain parts, I'll have flaps that fold out or tabs on the side so they can find them quickly," she says.

On the patients' side, their specific conditions will produce different requirements. Some patients who have chemotherapy suffer from peripheral neuropathy and can find it difficult to pick up paper, so Liz and Sarah recommend using extra thick or textured paper, and for those who may have poor eyesight it may be necessary to print in a large font.

Take advantage of digital

When developing a mobile app alongside printed materials, it can be tempting to copy the text across and leave things as they are. This wastes a valuable advantage of the digital world.

> "With an app or a website, you've got the vertical space... You've got infinite scrolling, so you've got the ability to break things down a little bit more, make things a little bit clearer."
>
> Sarah Gracey

And that is not all. "You can also make things interactive, which helps because some people learn things more effectively when they can interact with them."

You can also have variable font sizes and add buttons to help users navigate through the information, and you moreover, you are not bound to static images. Animations can be a fantastic way of explaining complex ideas as they let your audience literally see what you mean. They also help to overcome any other communication obstacles, such as language barriers — ideal for the patient who is not reading information in their mother tongue.

A final word

Patients have a right to know what they are agreeing to, and there is more we can do as an industry to help them understand their role in clinical trials.

There are several characteristics of the copy and layout of effective clinical trials materials that help ensure that no patient is left behind, and we must strive to adopt as many of them as possible when we produce new pieces.

We must also keep an eye out for new ideas — not just from pharma, but from all around us — that we could adapt for these purposes. And when we find something new, we must share it with our peers!

If you would like to find out more, or tell us about a tip that you have picked up, email us at: letstalk@cuttsyandcuttsy.com

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