



# Benefiting from Back Translations

Simon Andriesen at MediLingua discusses the language aspects of running multinational clinical trials and explores the unique solutions that are employed in the pharma sector

Language plays a critical role in clinical research. Trial sponsors, medical ethical committees, investigators, research nurses, patients and healthy volunteers all need to be informed about the ins and outs of the trial, and eventually the results of the research project must be published. Furthermore all this must be set out in clear, unambiguous language. During clinical trials a range of different documents are used. Many clinical trials cross national boundaries, and therefore must be multilingual in design.

The list of languages is no longer restricted to the ‘easy’ languages of the EU. These are still around, of course – and they now include many Eastern European languages – but trials in other territories are now run and these days trials often include study centres in Africa, Asia and Latin America. The advantages are clear: large numbers of treatment-naïve patients are keen to get involved. One stumbling block is the question of language. In some countries, it is not uncommon for people to speak one of possibly dozens of different languages or dialects. Many can’t read or write, making informed consent forms (ICFs) impossible to fill in. How can you make sure that a question in a questionnaire means the same in Zulu and in Urdu? And are questions about ‘minor discomforts’ answered differently in a rich Western country than in an area that was a war-zone a few years ago?

The issues around language (problems as well as opportunities) are generally poorly understood. Language is often not an issue – it is simply taken for granted – until something goes wrong: for example, because there is an error in one of the language versions of the ICF and participants have consented to something they were not correctly informed about, or certain questions in a questionnaire can’t be used because across the different languages the answers cannot be compared. Maybe language is not regarded seriously because, when compared with the total cost of setting up and running a clinical trial, the language related costs are relatively small.

## DOCUMENTS INVOLVED IN CLINICAL RESEARCH

The study protocol describes the background and purpose of the clinical trial, the possible outcomes, the profile and recruitment of patients, insurance issues, and so on. The ICF is another important document in clinical trials. Its purpose is to inform participants in the study – usually the patient suffering from a certain disease or condition. Under the Declaration of Helsinki – an initiative by the World Medical Association in 1964 (and since then updated frequently) – participants must completely understand the information provided, including the risks associated with using the study medication or treatment. They have to sign the ICF to state that they fully understand the information that was provided and are willing to participate. In clinical studies, patient reported outcomes (PROs) forms, such as questionnaires, are key documents; these are either filled in by the participant or, on the basis of an interview with the participant, by the investigator. The ICFs, PROs and questionnaires almost always have to be translated.

## TRANSLATION QUALITY

Translation quality is especially important when it comes to PRO documents, including questionnaires, instruments and scales. These have to reflect the nuances of the original; if questions in the questionnaires are not translated the exact same way across all languages, there is the risk that the answers to these questions cannot be pooled and that part of the valuable research data become useless.

Translation quality is also important because those volunteers involved have the right to be properly informed; trial results are often scrutinised by the authorities and if they find something that may not have gone according to the rules, part of the research data may not be usable. This may lead to additional research cost, and if it causes a delay in time-to-market that eats into the patent protection window, it also results in a considerable loss of revenue.

There are three main causes of problems with translated documents

- ◆ Limited experience of the translator (of course, a cheap translator fits a limited budget better than a professional one)
- ◆ Shortcomings in source text
- ◆ Lack of time

Problems resulting from these causes are all preventable: budget for and involve experienced, professional medical translators; test and carefully edit the texts before they are translated; and dedicate the amount of time it needs. All easier said than done, but it would be a good start if language aspects are taken into account early on in the planning process and not as an afterthought.

## BACK TRANSLATIONS

The world of medical research has adopted an almost unique translation review method, which is hardly ever used in other sectors: the back translation. A back translation is when a translated document is translated (back) into the original language. The idea is that the author or trial sponsor can verify whether the translation covers all aspects of the original. But, if the English back translation is the same as the original English version, this doesn't mean a thing. And if the English back translation is different from the original English version, this doesn't mean a thing either.

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) has evaluated a dozen existing guidelines concerning the translation of patient reported outcomes (PROs) and in formulating an integrated method to

produce language versions of PROs. This method includes a double-forward translation, a reconciliation of these translations, then a double back translation, again reconciliation, review, and harmonisation. While this can be considered the 'optimum' way to perform linguistic validation, it is a time- and cost-intensive process. The translation cost of a questionnaire that follows the ISPOR-procedure is at least five times as high as the cost for a single-forward translation and edit.

## TRANSLATION OF PROs SUCH AS QUESTIONNAIRES

Producing clinical trial questionnaires in different languages is one of the most sensitive translation challenges. Many different issues need to be taken into account. A single country may have a number of official languages: Belgium has three; Finland has two; and Switzerland has four. Swiss-German is different from German spoken in Belgium, while both are different from German spoken in Germany itself. French for France is different from French for Canada and French for the Western parts of Switzerland. Spanish is one of the world's most commonly spoken languages, but Spanish is different in Spain than in Latin America. And in Argentina, it is different from Peru, Chile, or Mexico, while the Hispanic population in the US speaks a different form of Spanish again. If this seems complex, consider South Africa or India, each with nine official languages that are legally recognised; in India there are dozens of additional languages, some of which are spoken by more people than Swedish.

But it is not only language that is the variable here. There are also differences in culture, literacy levels, understanding of certain concepts, and so on. Although all this is related to language, discussing all these aspects would be beyond the scope of this article.

## HOW TO PERFORM BACK TRANSLATION

Back translation is part of a process that generates language versions of questionnaires, measuring scales and so on; it is never a standalone event. These documents clearly are

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important; they are expected to generate research data that eventually have to be pooled into one analysable database, across all languages. So what does the process look like, and how does back translation fit in?

In most cases the (English) original is translated by one or more translators – native speakers of the target language. If several translators are involved, one of them evaluates the translations and ‘reconciles’ these into one version. The next step is that one or more back translators translate the reconciled version back into English. Again, if several back translators are involved, one of them evaluates the back translations and reconciles these into one version. The next step is to evaluate the reconciled back translation and compare it against the original English. The reviewer needs to be aware that the two versions are not going to be the same; if they were, that could be a sign that the back translator had access to the original (maybe because it was available on the internet). Any discrepancies between the original version and the reconciled back translation can best be resolved by having the author discuss these, with those who have performed the reconciliation of the translations and of the back translations. Most of the time the translation can then be accepted for further testing.

The back translator must be aware that the job concerns a back translation. This means he will stick to the source text a bit more than normal. It is especially important that small errors or weak sentences in the text are not ‘ironed’ away, which he otherwise would do. The main point of a back translation is obviously to find shortcomings in the original translation, and any errors must be marked and commented.

### COGNITIVE DEBRIEFING (TESTING)

After the translation/back translation process is completed, the final version of the translation is usually tested. In the world of clinical trials, this is usually referred to as ‘cognitive debriefing’. Most of the time, this step involves between five and 25 test volunteers per language version; they are interviewed on the basis of the translated questionnaire. During this test the questions are checked in order to establish whether they can trigger the correct answers and, in case optional answers are provided, whether or not these are clear enough. The participants are monitored for any sign of stress or discomfort and the interviewer should ask questions about the meaning of certain words used in the questionnaire to make sure that the questions are understood as fully as possible. The bottom line is that questions in any language concerned should all mean the same; if this is not the case, the answers in France, for example, can’t be combined with those in Germany, India and Peru.

### THE UNPOPULARITY OF BACK TRANSLATIONS

Apart from the high cost (one can think of more cost-efficient ways to ensure translation quality) a lot can be said

### About the author



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in criticism of back translations as an efficient way to check quality. Many translators even argue it is a waste of time and money and that it does not generate any meaningful feedback – and, indeed, if a back translation is not done properly, they are right. However, if it is properly performed and dealt with as one step in the process, it can make sense, although perhaps not for all languages and always at relatively high cost. If there are discrepancies between the original version and the back translation, this may be caused by shortcomings in the source text, or by errors introduced by the ‘forward’ translator(s), the editor of the forward translation, the back translator(s) or by any combination of these persons.

It can be argued that back translations are less relevant for languages with an established ‘translation infrastructure’ (such as French and German), provided that qualified translators have been used for the forward translation. Increasingly, clinical trials are held in countries in Eastern Europe, Africa, Asia and Latin America. Languages such as Lithuanian, Kurdish, Zulu, or Indian, may not (yet) have established terminology standards; in such cases a back translation may indeed be a good way for a sponsor or CRO to check the forward translation. However, there are very few qualified English medical translators who can work from such languages, and for some language combinations back translation may simply be impossible without improvising a solution that does not involve a native speaker of the back translated target language (English).

If back translations are merely done to be kept on file or to satisfy ISO auditors, the efforts and cost are a total waste. When taken seriously and done in a professional way, a back translation effectively can identify the shortcomings of a translation – although one may argue whether it is cost-effective. A final edit stage, with a detailed commentary or a double forward translation, will probably provide the same level of confidence. ♦