

# Lost in Translation?



## *Challenges in Preparing Participant Information for Multilingual Studies*

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*Keywords: Idiomatic language, Informed consent, Lay terminology, Participant information, Translation*

**A**N INCREASING NUMBER of studies are being performed in parts of the world whose first language is not English. Globalisation of clinical research raises serious questions about the ethical and scientific integrity of this trend and who really benefits from it.<sup>1</sup> The article cited reviewed 300 articles from the New England Journal of Medicine, The Lancet and The Journal of the American Medical Association between 1995 and 2005. It showed that the number of countries outside the USA containing clinical trial sites more than doubled from 33 to 70 over the 10-year period,

while the share of overall trials conducted in the USA and Europe declined from 53.8% to 42.6% and from 40.0% to 36.5% respectively.

There are challenges in translation and communicating science in a multilingual world dominated by the de facto language of English. The European Union alone has 23 mother tongues. About 1.2 billion people may speak English as a second language, while only 380 million can be considered as native speakers, a ratio of 3:1.<sup>2</sup>

Translation carries the risk of misinterpretation; this is an important

consideration in all documents we translate for clinical trials. In this article, we look at the issues surrounding translation of the patient information and informed consent forms (ICFs), the written information that is provided to the trial participant as part of the consent process. Clinical trial ICFs range from 2,500 to 4,000 words or even longer, which has the potential to provide information overload to a participant. While this is not the issue being considered here, it can be also viewed from the perspective of the translator.

The pharmaceutical and medical device industries are driven by timelines and quality. Translation is a relatively slow and costly process. The smallest delay or translation

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error can have resounding implications. It is important to get it right ‘first time’. If an error in the ICF goes unnoticed for some time it could have significant consequences to the study participant or the trial outcome.

### **Translation: The process**

□ INITIALLY, ICFS ARE usually prepared in English. As we know, they should be written in a format that is easily understood by the trial participant and, in most cases, in ‘lay terms’. By ‘lay terms’ we mean that the document should be written in simple English for a reading age of an 8-10 year old or at a level the average ‘Sun’ reader can understand. Institutional Review Boards (IRBs) in the USA set an arbitrary grade level of the 6th-8th grade. The Flesch Reading Ease Score describes materials at 6th-8th grade reading level to have 14-17 words per sentence and 139-147 syllables per 100 words.<sup>3</sup> This means that most words should have only one or two syllables. If ICFs are not written to this standard, as we all know to our costs, they may be rejected by Research Ethics Committees (RECs)/IRBs. This article is not aimed at defining how we achieve the correct level of English in the initial document, but it is important to consider that if this initial document is not prepared correctly, the translation process will be even harder.

Once we have obtained a well-written English version, the next step is to translate

the document into the ‘mother tongue’ of the trial participants. As we have said, it is important that the ICF should not be highly complex, but it is inevitable that certain scientific words or phrases will be used. Some of the most successful translations we have seen have been performed by (or at least involved as a reviewer) a medically-qualified person. The medical background of the translator or reviewer is important to understand the nuances of the terms used, to ensure that they are best fitted to the correct term or word in the target language.

As with all written documents, it is important to understand your audience; in this case it is not only the participant but the translator we need to consider. We need to identify our assumptions and ensure our audience understands them. If the translator does not understand then we need to look at a different approach. We must never assume we are all the same: we are not.

The ICF needs to be independently translated into the target language; this is often referred to as the ‘forward’ translation. If changes are now required they are added to this forward translation (adapting it to local specific requirements). The forward translation is then ‘back-translated’ into the original language (usually English) by a different translator. The back translation can then be compared to the original source

and checks made for any discrepancies and modifications that have been added. It is important to remember that a back translation will not be a mirror image of the original English version but the meaning and nuances should be compared and verified. Any issue or questions raised at this stage must be resolved.

A final version is then produced. All versions need to be dated and version controlled. Translation logs should also be maintained to document the process. It is important to remember that if modifications had been made to the forward translation: these need to be identified with a version change.

### **Translation: The theory**

□ WHEN TRANSLATING, IT is important to know the country by country requirements in order to determine the languages to which you would like to translate the ICF. Israel, for example, requires informed consents in Hebrew and Arabic, but many RECs also ask for a Russian version as the Russian population has grown significantly. The UK RECs have a question on their submission forms asking whether the ICF would be available in other languages and we were once asked by a REC to provide a version in Hindi.

There are numerous English words that have been adopted by other languages. For example, the word ‘compliance’ has been accepted as a technical term in German and this word therefore has no need to be further translated. The translator can sometimes translate every English word in the source text to the target language.<sup>4</sup> However, the word ‘protocol’ has different meanings in different languages, to the extent that the committee preparing the ISO14155 standard had to use the term ‘Clinical Investigational Plan’ instead to facilitate translation to many languages.

Translation can sometimes change the ICF from a ‘lay term’ document to a scientific one. This is more difficult to identify and requires a native speaker to read the translated document. One of the most valuable sources of ‘validation of lay terminology’ in the target language would be a study site coordinator in the target country.

The more challenging aspect of translation does not involve single words but whole phrases. If the translator translates every word from English to the target language, this can lead to unidiomatic text. In such a case the translator needs dissociate themselves from the source language to find the most adequate and idiomatic means of expressing the concept in the target language. We have heard of many occasions where nuances are lost in translation, so much so that the actual meaning of the phrase

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is changed or distorted. If left unchecked, this would have a significant effect on the information provided to the trial participant and possibly the outcome of the study.

Good translation is all part of successful cross-cultural communication. Idiomatic phrases are a particular problem, as they differ dramatically between cultures.<sup>5</sup> Sentences should be short. It is important to simplify each sentence in the original source so the parenthetical information and clauses are easier to identify and understand. It may also be worthwhile to review your text for possible ambiguous terms or phrases. In the English language, we use many synonyms; it is recommended to use simple words when a document needs to be translated so we must learn to suppress our creativity with the English language.

Good translators will ensure that any words or phrases that do not translate well are highlighted and possible alternatives discussed. If you receive questions from your translator, this should be viewed positively, as it means they are critically examining your document and this should lead to a better quality product.

An experienced translator can translate approximately 3,000 words a day.<sup>6</sup> However, there are now translation software packages, which can speed up the process.

Often, ‘certified’ translations are requested. Certification means many things depending on the country you are working in. Non-accredited translators can produce work of an equally high standard as certified translators.

### **Translation issues**

CERTAIN WORDS AND phrases cannot be translated into the target language because equivalents or even entire concepts do not exist in all languages and cultures. Translation of any documents that need to be provided to clinical trial participants need special consideration to ensure they take into account the culture of the country or region.

People who can simply speak two languages fluently may not necessarily be able to translate effectively between them. It is important to use someone who has experience of translating ICFs, knows what is required in these documents and where the pitfalls are as well as having the necessary medical knowledge, or access to this during the review.

One of the aspects that can be especially difficult to describe is the use of placebo. In some developing countries, the participant may not fully understand the concept of placebo nor any of the associated risks that can be involved in a clinical trial. Precise translation is vital in this aspect of the translation process.

It is usually more important for the translator to be fully fluent in the target language, although control of source language is important as well. This is due to the fact that the source language is written in lay terms and it is a challenging job to bring a document to that level. Inexperienced translators who are not familiar with these requirements tend to use the ‘more correct’ terminology

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and in a recent translation performed by a sponsor a Belgian ethics committee rejected the information sheet because it was written in language that was “too academic”.

Translators may forget to translate just one word, which could, in turn, change the meaning of the entire sentence or even put a patient in danger. For example, forgetting to translate the word “not” in an information sheet warning “not to get the external insulin pump wet” could have dire consequences. Validation of the translation must be done very carefully, making sure all the words have been translated and the meaning of the sentence remains the same.

Our experience shows that translations of ICF and patient questionnaires can, in some cases, be very challenging. We once encountered a patient questionnaire question that asked about normal day to day activity that was translated in a way that could be interpreted as “do you hit your partner on a regular basis?”

It is important to establish realistic deadlines. Putting the translator under unrealistic time pressure may lead to a poorer quality translation. We encountered cases where the translators were in such a hurry to deliver the translation they left complete sections in the

source language in the documents (as they did not have time to quality control their own deliverables). You should also make sure the text is finalised before sending to the translator. Revisions and re-translations will cause delays, additional expense and potential problems.

### **Conclusions**

□ TRANSLATION IS HERE to stay; the world has opened up and there are relatively few areas where clinical studies are not being conducted. Most clinical trial participants are not bilingual and rely on a well translated ICF as part of the informed consent process.

A poor quality translation can lead to an increase in total cost of trials or ultimately a delay in a drug reaching the market. It may lead to lawsuits or rejections by regulators and can affect the safety and efficacy of the marketed product.

It is important to choose a translator who has a sound process for translating, which includes both linguistic and medical reviews. A procedural approach, driven by SOPs, will ensure that not only the words or phrases are correctly translated but the correct meaning has been provided. Translators should have a recognised qualification or proven experience

*“... it will become increasingly important to test the translated ICF (perhaps involving patient groups) before use.”*

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in translating ICFs. In some cases, accreditation may be a valuable requirement, demonstrated by some sort of certificate; however, this does not guarantee quality of the final product.

It is important for translators used by companies to be screened. The authors have relatively recently started to audit our translation providers, following a similar process to other vendor audits. Many companies do not audit translation companies, but we think it is a valuable approach to ensure quality of study documents, especially to ensure that the study information has been provided correctly to participants in our clinical trials.

When outsourcing translations to companies whose quality of work is unknown, it is also vital to perform a separate review or QC step, to ensure there are no translation errors.

In future, we feel it will become increasingly important to test the translated ICF (perhaps involving patient groups) before use.

This article does not address the broader issue of the readability of ICFs. To be able to read an ICF is one thing, to be able to understand what has been written is quite another. The written ICF should enhance the process of consent; this written document can be re-read at the subject's or their family's leisure. ICFs are becoming more akin to legal documents; however, when we write and translate these documents we, usually, do not involve legal review. The authors have seen a recent trend where several large sponsor companies are having ICFs reviewed by lawyers, which (of course) leads to more delays in study start-up. If we do not provide more sensible documents in future, perhaps we will all need to take this route. That is another topic for another time...

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