

Written and researched by:
Kirk Mousley of
Mousley Consulting
and Bob Muzerall of
ForeignExchange
Translations

In the next issue of
EDC Today:

Informed Consent
and Bias

About EDC Management:

EDC Management is the leader in Clinical and Data Management and Electronic Data Capture (EDC) consulting services for the biopharmaceutical industry. EDC Management publishes well-researched and timely information about Electronic Data Capture technologies and processes through EDC Today[®] and EDC In Depth. We do not sell or endorse any specific EDC software application or vendor. Improve process today; position for tomorrow.

EDC Management

P.O. Box 23
Conshohocken, PA 19428
484-530-0300 (voice)
610-567-0357 (fax)
info@edcmanagement.com
www.edcmanagement.com

Translating Study Materials

EDC Today is an independent publication on current information and issues in Electronic Clinical Systems (ECS) strategies and technologies for the Biotechnology and Pharmaceutical (Biopharma) industry. Each month we examine topics related to ECS theory, technology, practice, or implementation.

EDC Management is increasingly being asked many questions about global clinical trials and foreign language translations, with emphasis on what needs to be translated and why. This topic has recently been in the press. Both in February and in June, the Association of Clinical Research Professionals' (ACRP's) Monitor magazine featured articles on performing global clinical trials. Biopharmaceutical companies are increasing the number of global trials they perform for several reasons; among them are perceived lower cost of clinical trials and anticipated greater patient populations.

In this issue, we briefly describe the need for language translation, but focus more on describing some issues with translation and stressing the need for companies to adequately verify the resulting translations. We will also touch upon some tools used in translation, and describe the difference between translation and localization.

Introduction

The biopharma industry is facing significant challenges. Business has now moved offshore and the industry must attract new buyers for their products. It is reaching all corners of the world to sell its products. With this growth comes a problem: how does one overcome the language barrier? And, how does one ensure patients accurately understand their role in the clinical process? Success with this problem can mean growth, and failure can mean a giant step backwards.

This article will describe how translations of clinical material are performed, and the steps taken to insure accuracy. It will then explain some of the technology used in the language translation industry, and describe localization and illustrate how it differs from translation. In closing, it will touch upon some interesting translation issues.

(continued on page 2)



The Need for Translation

Translations for clinical trials can be broken down into two categories: translations for regulatory professionals, and translations for patients. We break this down into categories because regulatory professionals usually have a higher level of understanding with regard to the content of the documentation, and because the documentation is weighted more toward scientific terminology. Translations for patient-related documents need to be more colloquial and must explain complex scientific concepts in every-day local language.

Translation for regulatory professionals includes documents such as the protocol and investigator brochures. Translation for patients includes documents such as informed consent and the patient reported outcomes (PROs) which include diaries, surveys, and QOL forms.

The Translation Process and Quality Assurance

The process of translating sounds simple. A linguist would read the source document and translate it into the target language. Unfortunately, it is not that easy in practice. Languages do not always map word to word, and phrases in one language (especially idiomatic phrases) may not make sense in the target language.

To understand the translation process better and to ensure quality, we need to start at the very beginning – the source document. If the source document is not clear and concise, the resulting translation will reflect the imperfect source document. For example, a Case Report Form (CRF) question that asked “Time of medication” is not as clear as “Record the time the last study medication pill was swallowed.” Therefore, a quality translation is dependent on the quality of the source document. Some biopharma companies have instituted a “standardized” wording approach to improve quality of their translations. Examples of this can include using active versus passive voice and the avoidance of multiple modifiers.

A second consideration for translation quality is the linguist. The linguist must not only be a native speaker of the target language, but also be knowledgeable about clinical trials. As a first and second round of quality checks, a separate editor and proofreader, both independent linguists trained in the clinical area, should assess the translated document.

Once the clinical document has been translated into the target language, a final quality step needs to be taken. This final step would include either an in-country review or a back translation.

An in-country review is common for products already approved for sale or for large biopharma companies with local support in the countries receiving the translated material. The in-country reviewer will read through the translated document and make editorial comments based on his knowledge of the product and his knowledge of the language. These comments are then integrated into the translation, assuming they are not in conflict with the biopharma’s business rules. The advantage of an in-country review is that the translated document is viewed by an in-house professional that understands the particulars of the clinical trial. The disadvantage is that the process takes valuable time from the reviewer who might best use his time for his assigned work.

(continued on page 3)



A back translation is more common for clinical trials material. In a back translation, a second linguist will translate the already translated document back into the source language. The two versions of the source document (the original and the back-translated one) are then reconciled to arrive at a quality product.

A back translation often gives widely divergent translation results, especially when no words in the target language can be used to reflect the meaning of the source word. Hilary Davies of Foreign Exchange Translations in her article, “Translation and Back Translation in the Drug Industry” states:

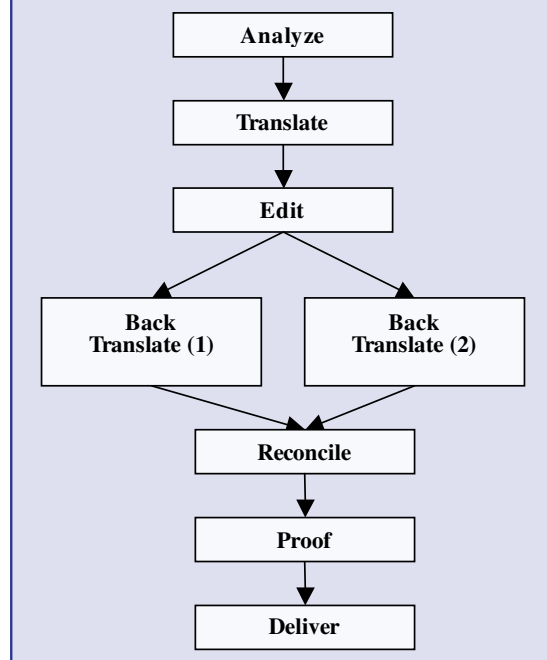
Back translation hinges on the idea that the back translation and the source can be lined up and compared against one another. However, any translation that is done well will depart from the semantics and structure of the original source language in order to meet the requirements of good style in the translation. Grammar is inherently diverse across different languages, and the translator will retain the meaning of the translation, rather than the original grammatical properties of the source text. A back translation comparison should essentially ignore syntax and focus on the comparative meaning of the two texts.

Back translation should be employed with caution. When comparing back translations against the source material, reviewers should be aware of the importance of meaning versus semantics. Syntactical or stylistic differences such as “November 12th, 2006” and “11/12/2006” should be viewed as having the same meaning. Back translation, a costly and time-consuming procedure, can only be successful if this concept is understood.¹

The stated process of translating, editing, proofing and assuring quality (in-country review or back-translation) works well for most clinical documents. However, as stated earlier, a patient might need a more culturally valid translation in order to clearly understand the questions and his/her response to them. This step is commonly known as cultural validation.

Cultural validation is an additional series of steps to align the translation with the local colloquialisms and gear it to the patient’s educational level. This is accomplished by reconciling a forward translation with two back translations as seen in the work flow chart in Figure 1. Further, a specialist trained in local culture performs the reconciliation. This extra work is time consuming and expensive, but it might be worthwhile to assure quality for some areas of translation such as surveys and diaries. A final technique can be used to provide an additional level of quality assurance. This is often called cognitive review, and is accomplished by a trained specialist interviewing the patient following a survey to insure the questions were properly understood.

Figure 1. Translation Flowchart



(continued on page 4)



There is a database of instruments (questionnaire forms, etc.) that can be used that was developed by Mapi Research Institute and managed by Mapi Research Trust (Lyon, France).² The <http://www.qolid.org/> website describes how to access this database, and lists copies of 608 translations of some of these 583 different PRO instruments. The use of this resource or others like it can eliminate the need for costly translation.

Translation Technology

Translation Technology can be broken into two different categories. The first category is software applications that translate the source document into the target document automatically. These applications are referred to as Machine Translation (MT). The second category is database software that is used to assist translators in storing and retrieving translated strings for reuse.

At its basic level, MT performs simple substitution of words in one language for words in another (transliteration). According to Beshar Bahjat of InterPro Translation Solutions:

Machine translation tools work without a human translator and automatically translate text from one language to another with varying degrees of success. They can be useful in gaining an understanding of foreign content or a foreign Web site. Even so, none can automatically translate documents or Web content sufficiently well enough to eliminate the need for a human translator.³

The second category of translation technology involves a database, which stores phrases and idioms in a translation dictionary. This database dictionary is referred to as a translation memory (TM). Bahjat says:

Some translators find it requires more effort to correct the automatic rough translations generated than it does to translate with a translation memory tool. Coupled with the urgency of delivering the final product, building MT dictionaries to refine automatic translations is frequently not an option given the short lead times provided by many clients.⁴

Many translation companies build Translation Memories (TMs) for each of their clients to reflect how clients want certain phrases translated. An advantage to a TM is that it grows over time increasing the consistency and reducing the cost for the translation. In addition to TMs, these companies also compile style guides and glossaries for each client. The style guides help the translators set up the target documents in a uniform fashion, and contain things like money symbols, date formats, number formats (e.g., comma versus decimal point), and other conventions suitable to a particular locale. The glossaries are helpful for the translators to understand the intended use of the terminology.

Localization

Localization takes translation a step further. According to the web site <http://www.thebigword.com/Localisation.aspx> translation is part of localization, but localization adds cultural concepts to the translation:

For a translation to be localised it must be matched to the cultural requirements of the target market, ensuring any images and concepts are culturally appropriate.

(continued on page 5)



Taking website localisation as an example, the text on a website can be translated quite easily, but any cultural references, photographs and diagrams must be adapted to fit in seamlessly with the target market.

thebigword only uses highly qualified linguists who translate into their mother tongues and are fully immersed in their own cultures. After all, if you're launching an English spell-checker, you need to be sure if it's "aluminum" or "aluminium" "color" or "colour?" or indeed, "localization or localisation".⁵

Language translation companies should provide native translators that live in the target country or region. These natives should be able to confirm the proper use of cultural specific expressions.

Translation/Localization Problems

Examples of translation and localization difficulties abound. In many ways, this area of language usage and translation is most intriguing to the authors.

Hilary Davies in her article, "Translation and Back Translation in the Drug Industry" shares a number of examples that relate to the problems of back translations. One of her examples is:

The concept of meaning has been long researched and documented by translation theorists and academics. For example, the noun "work" can be synonymous and equivalent in meaning both with "literary masterpiece" (e.g. "a work of Shakespeare") and "place of employment" (e.g. "workplace"). At a word-to-word level, equivalence in meaning can be useless; already we are beginning to see the importance of context in any given text.

English source	Spanish translation	English back translation
Work	Trabajo	work/job/paper
Work	Obra	result/work/deed

With no context, the back translator has no way of knowing which sense the original English had.⁶

As another example, consider the following from Liesl Leary, of ENLASO:

Localization extends beyond just words. For example, here's a sign found in an inn in Switzerland:

Because of the impropriety of entertaining guests of the opposite sex in the bedroom, it is suggested that the lobby be used for this purpose.

In this example, the translation is perfectly fine. But it's not well localized. Here's why:

- In the United States, what we do in the privacy of our own bedrooms is practically a constitutionally protected right.
- In Switzerland, however, government intervention is not particularly frowned upon.

(continued on page 6)



- What we do in the privacy of our own bedroom with members of the opposite sex may not be appropriate for the lobby of a public hotel. This is probably also true in Switzerland but they mistranslated what they really meant. Their real intention was probably more along the lines of "please use the rooms for sleeping only".⁷

As these two examples show, translation can be quite interesting to say the least.

Conclusion

Contemplating the complexities of translating forms and documents accurately can be daunting. Failure can be costly. However, by careful study and good planning success will happen.

When asked to summarize the most important items to ensure quality translations, the authors suggest:

- Adopt standardized wording for all publishing.
- Build glossaries of specialized key terms. Have the glossaries translated by competent linguists, then validated by in-country reviewers.
- Work with a competent translation agency to build clean translation memories.
- If there are existing memories, have them validated by the agency working with in-country reviewers.
- Track reviewer changes to hopefully show trends indicating fewer revisions over time. The goal is to get the linguists and the tools good enough to stop reviews or back translations.

EDC Management wants to stress standardization. Adopting standardized wording is important to create clear concise source documents. It is also important to reuse as much as possible down to the level of phrases or paragraphs to simplify translation and provide consistency to the final document.

Finally, we suggest you work with a qualified group of linguists or a full service translation agency. They can help guide you through the morass of translation, and to help keep everything you publish as clear as if it were written locally.

Resources

¹ Hilary Davies, *Translation and Back Translation in the Drug Industry*.

² <http://www.qolid.org/>

³ <https://www.illinoistech.org/technologynews.aspx/678>

⁴ *Ibid.*

⁵ <http://www.thebigword.com/Localisation.aspx>

⁶ Hilary Davies, *Translation and Back Translation in the Drug Industry*.

⁷ http://www.customersat.com/Resources/Newsletter/Q2_2006_Leary.htm



Who's behind the research?

Our lead researcher, Kirk Mousley, PhD received BS and MS degrees in Electrical Engineering from MIT and a PhD in Computer Science from Lehigh University. He has been the President of Mousley Consulting, Inc. since its founding in 1993 and has directed the company's efforts in the areas of clinical database design, data editing/cleaning, document management, and submissions.

Karl Mousley received his BS in Mechanical Engineering from Rose-Hulman Institute of Technology and a MS in Computer Science from Villanova University. He has been a senior member of the technical staff at Mousley Consulting, Inc. since 1993. Among his significant accomplishments are the investigation, evaluation, and implementation of new computer technologies for clinical data management systems and developing strategic plans for integrating these technologies into current systems. He has extensive experience preparing Standard Operating Procedures (SOPs).



EDC Today* and *EDC In Depth

EDC Management publishes well-researched, timely information about EDC technologies and processes.

EDC Today is a free electronic technical bulletin.

Each month we examine topic areas related to Electronic Clinical Systems (ECS) theory, technology, practice, or implementation.

Each *EDC In Depth* research report comes with an executive summary and may be purchased individually for \$395 or as a group of related reports for \$975. Available via downloadable electronic version or paper version sent via mail.

To subscribe to ***EDC Today*** or purchase a specific ***EDC In Depth*** research report:

Order online at
www.edcmanagement.com

Email us at
info@edcmanagement.com

Call us at
1-484-530-0300