# GAINED IN TRANSLATION

JESSICA EKER and JENNIFER PETERS, regional directors of business development specializing in the life sciences industry at TransPerfect, discuss the translation process.

**Please give a brief description of the comprehensive process required for accurate translation of Patient Reported Outcomes.**

**JE:** The translation process for Patient Reported Outcomes is a very specialized, detailed methodology, involving many more steps than a straight translation process.

The process begins with a preparatory step, to assess the instrument. This includes looking over the key concepts within the source and identifying anything that may not be entirely comprehensible. In this step, concepts requiring clarification are identified and confirmed with the instrument developer. In my experience, it is always best to have some degree of communication with the developer throughout the life cycle of the project so that if issues or questions do arise, someone is available to address them as quickly as possible.

The next step involves forward translation, editing and proofreading. At TransPerfect, this crucial step is an ISO 9001:2000-certified process, where there are two separate teams of three linguists – translator, editor, and proofreader – who would translate the instrument, producing two translations. The editor then reviews and refines the document to ensure that it reads as if it were originally written in the target language. Finally, the proofreader checks the translation against the original to verify that it appropriately represents the source.

Next, a third, independent native speaking linguist reconciles any differences between the translations. This process addresses any discrepancies and the linguist then prepares one final reconciled version of the forward translation.

Next, an independent native speaker of each target language performs the dual back-translation. The purpose of back-translation is to unveil to native speakers of the original source language how the message is being delivered to the target audience. Any discrepancies are addressed in the next step – the back translation resolution process.

Here, any objective differences between the source document and the back-translation are reconciled, and key concerns are discussed. A tracking document is generated that details each word, phrase or sentence under scrutiny and the manager of the project coordinates with the appropriate personnel and the relevant linguists in order to select the most suitable wording for the final translated text.

The next step is the Cognitive Debriefing, or pilot testing phase, that can proceed with either patients or linguists. In my experience, if the work is done with patients, the client oversees the sourcing of them. Typically, four to six patients or linguists assess the level of comprehensibility and cognitive equivalence of the translation, test any translation alternatives that have not been resolved by the translators and highlight any items that may be inappropriate conceptually. The manager of the project develops a questionnaire to accompany the instrument, which will be provided to the individuals in each of the target countries, so the translation of the instrument is actually tested out on a target population. A key component of the debriefing stage is to actually observe the patient or linguist responding to the instrument and questionnaire to visually assess body language.

All responses are analyzed by a project management team, who make determinations regarding any further changes to the translations. A matrix presents the finding of the survey as well as any necessary explanations. The goal of this step is to discover any issues or potential sources of misunderstanding that have not been previously identified. This confirms that the translation has conceptual equivalence to the original instrument.

After the cognitive debriefing stage, a final proofreading of the instrument is conducted where any results from the debriefing stage are incorporated into the final draft of the translation. Finally, an independent linguist for each language with no prior affiliation with the instrument will proofread the translation and make any necessary corrections.

In conclusion, the project manager presents a final report, detailing every change made throughout the linguistic validation process, including explanations for translation and word choice. There will also be a summary of the cognitive debriefing results included in this report.

**Why not just translate QOLs – what's the need for so many steps: preparation, back translation, proofreading, cognitive debriefing?**

**JE:** So many steps are required to ensure it is as conceptually equivalent to the source instrument as humanly possible. All of these additional measures beyond just straight translation ensure an unbiased result, which is of course the ultimate goal.

**During the translation process, what cultural differences need to be taken into account when developing an international patient recruitment campaign?**

**JP:** It is not just the accuracy of the text being translated, but how a message is conveyed that is of critical importance to a successful campaign. One should start by considering how each culture views clinical research in general, and structure the campaign accordingly. The content and graphic design should be customized to the desired target patient population. Being culturally aware and sensitive will equate to the creation of more appropriate recruitment materials and ultimately a better overall result for the campaign.

**When should translation be considered as part of a global clinical trial?**

**JP:** Ideally, translation would be considered in the planning stage of the trial. Once countries have been identified to be included in the global trial and the documents are in development, translation should be an integral part of the planning process.

Considering translation at the start of a trial will allow resources to be allocated more efficiently, timelines to be maintained, and will generally provide more culturally- and linguistically-appropriate clinical documentation. Selecting a translation partner with the scalability to meet demanding project deadlines and significant clinical trial experience will assist the CRO or pharmaceutical company to develop a translation strategy. The ability to execute that strategy globally will result in more accurate and timely data collection.

**There has been widespread adoption of clinical technologies such as IVRS and Patient Diaries. What considerations affect the collection and translation of data?**

**JP:** Generally, life sciences companies do not have all of the necessary resources or highly-specialized linguistic talent to manage the translation process without an experienced vendor. One of the primary considerations should be vendor selection. When evaluating potential localization partners to assist with the use of IVRS and patient diaries, it is imperative to choose a company that is as much a technology company as it is a language services provider. The ability to work with an organization that has an in-house studio and audio and software engineers on staff will help to alleviate some of the challenges that arise when utilizing IVRS and patient diaries.

There are a number of considerations that affect the data collection and translation of IVRS and patient diaries materials. For IVRS, it is necessary to use highly-qualified linguists familiar with IVRS terminology. Due to scheduling demands, companies find it extremely valuable to receive translations under quick turnaround times. Also, the ability to provide well-trained, 24-hour multilingual call center support for the IVRS help desk, will help to alleviate some of the communication issues that may be experienced when conducting global clinical trials. With regard to patient diaries, one must consider the length of questions and character limitations when the questions are translated. Also, it is necessary to QA the device after being localized to ensure that all of the text is appearing fully and that no text is being truncated or obscured.

**What are the best and most challenging aspects of an ePRO implementation?**

**JP:** The main purpose of ePRO implementation is to collect faster, more reliable data through the use of technology. There are many benefits to an ePRO implementation. By using a portable handheld device, patients are able to report more consistently and accurately. Compared to the paper method, ePRO allows for more reliable data because one is not relying solely on a patient's memory, for example. There are reminder alarms as well as date/time certainty when the data was input. Typically, questions cannot be skipped in ePRO, which alleviates some of the missing data that may not have been collected on paper if the patient decides to skip questions. Also, by using a device, the illegible handwriting issues that plague paper reports are no longer an issue. The main challenge of an ePRO implementation would be the initial investment for hardware and training.

**Fast data turnover is essential to saving time and money for pharmaceutical and biotech companies. Do you have a strategy in place to ensure the translation process is as swift and as smooth as possible?**

**JE:** Yes, we have implemented a stringent, ISO 9001:2000-certified process to ensure the smoothest system. For straight document translations our turnaround times are about 25 percent to 30 percent faster than the industry standard and for linguistic validation, they're about 50 percent faster. The two main reasons I believe we achieve the fastest turnaround times while maintaining quality are: First, we have over 4,000 linguists in our pool of resources. We have numerous linguists that are specialized for each given subject, in order to avoid any imposition of further delays on our end. In addition, all of our linguists will not only be native speakers of the target language, but also will have at least 10 years of experience translating in their specific subject matter – whether that's for the oncology therapy area, cardiovascular, etc.

The second reason why we can have naturally-accelerated turnaround times in comparison with the industry is because we have four production hubs. So feasibly, if a client needed to initiate a project, and it was 11:00 at night, we could begin the project out of either our Hong Kong or Honolulu production hubs and effectively use the world's clock to our advantage, then bring the project back home to our New York production hub at 8:30 am New York time the following day. Overall, being one of the most experienced firms in the industry, we have unparalleled capabilities within the life sciences field because we thoroughly understand the needs and demands of this highly-regulated industry as well as the nuances and complexities of translation.

**Jennifer Peters** is Regional Director of Business Development for TransPerfect Translations International Inc. She specializes in consulting to the Life Sciences industry and developing key relationships at TransPerfect. She is also Regional Director of both the Boston and Philadelphia offices.

**Jessica Eker** is Regional Director of Business Development for TransPerfect Translations International Inc. She is responsible for global business development and client services in the Life Sciences arena at TransPerfect. She is also Regional Director of the company's New York, Montreal and Toronto offices.