Breaking the Language Barrier

Jessica Eker at TransPerfect Translations looks at the key steps for success in linguistic validation

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. Jessica is also Regional Director of the company's New York, Portland, Montreal, Toronto and Vancouver offices.

To anyone in clinical research, patient-reported outcomes (PROs) are familiar and critical tools for gathering valuable insight into symptoms, side effects and safety, with regard to drugs under study. Compiling this information is a necessary and important step in getting a particular treatment from the lab to hospitals and pharmacies. However, as clinical trials become increasingly global and reach into more diverse cultures, a number of complicating factors can make this stage among the most challenging in the process of obtaining regulatory approval.

During the PRO stage, which typically occurs in the late phases of clinical trials, written or oral surveys are conducted so that patients can provide information about their medical history and their experience of a given treatment. Naturally, pharmaceutical companies face the inherent hurdles of evaluating patients' qualitative responses and transforming them into quantitatively valid results. The expansion of global trials has further complicated these hurdles and created additional barriers requiring a level of expertise all its own. Conveying technical information to large groups of people from different cultural and educational backgrounds, as well as integrating those responses from Japanese, English, German and Spanish into a single language, creates an entire additional process when assessing PROs.

Linguistic validation is a methodology that allows researchers to better manage the complexities of international studies by preparing a cognitively equivalent instrument – a document that, when presented in aggregate, will approximate the same meaning across diverse linguistic and cultural groups.

In the process of linguistic validation, linguists perform several rounds of translation and then submit the document to native speakers who carry out the cognitive debriefing, or pilot testing. Though the methodology for the linguistic validation process has become better defined over the past decade, workflows still vary between organisations that offer the service. Non-regulated parts of the process – such as instrument delivery to the various sites and verbal, unscripted instructions given to patients by the in-country investigators – can further compromise the results if not clearly established in advance. Therefore, it's of critical importance to be completely familiar with every aspect of linguistic validation and to take a holistic approach in identifying and addressing contingencies that may arise. Additionally, companies can count on better outcomes, and complete the clinical trial process faster and with a higher degree of accuracy, when they view linguistic validation as one part of a whole clinical trial process.

KEY STEPS TO SUCCESS

When assessing PROs, language and cultural considerations must be taken into account. In order for an instrument to be practicable in international studies, it needs to communicate the same concepts in all languages. This allows for pooling data and comparing results across countries. Most instruments are originally crafted in one source language and are targeted to a single culture. Having to adapt the content to other languages and cultures entails a process that is more specialised and detailed than that performed for a standard document translation.

Language and cultural considerations must be taken into account to ensure accurate PROs. In order for an instrument to be practicable in international studies, it needs to communicate the same concepts in all languages. This allows for pooling data and comparing results across countries. Because most instruments are originally crafted by American firms in English, they are targeted to a single language and culture. Having to adapt the content to other

languages and cultures entails a process that is more specialised and detailed than that performed for a standard document translation.

A PRO translation project begins with a preparatory step in which the instrument is assessed. Problematic concepts are identified and submitted to the instrument developer for clarification. The next step involves either single or dual forward translation, editing and proofreading. During this process, one or two teams (depending on whether single or dual is requested) of three linguists produce their own translation of the instrument: the translator renders the text into the target language, the editor reviews and refines the document to ensure that the text reads as if it were originally written in the target language, and the proofreader checks the translation against the original to verify that the source language is accurately reflected.

All the documents are then reviewed by an independent linguist who is a native speaker of the target language. If any discrepancies are found, this individual will resolve them in order to create one final version of the forward translation. Next, a dual back translation is performed by native speakers of the source languages so that an understanding can be gained as to how the message is being delivered to the target audience. After all discrepancies have been reconciled, a tracking document is generated that details each word, phrase and sentence under scrutiny, and the manager of the project coordinates with the appropriate personnel and the relevant linguists in order to select and implement the most suitable wording.

Once the translated instrument has been established, the cognitive debriefing stage can begin. Typically, four to six patients or laymen assess the level of comprehensibility and cognitive equivalences of the translation, consider alternative translations, and highlight any items – by way of oral interview – that for any reason may be inappropriate by way of oral interview. Throughout the cognitive debriefing interview, the participants are observed responding to the instrument and questionnaire so that their body language can be assessed.

After the translated document's cognitive equivalence to the original instrument has thus been confirmed, any complementary suggestions from the debriefing stage are evaluated for possible incorporation into the translation. The resulting text is reviewed by another independent linguist, who will ensure the integrity of the final version of the translation. At the end of the linguistic validation process, the project manager presents a final report that details and explains all edits and summarises the cognitive debriefing results.

WIDENING THE SCOPE

Since workflows can still vary from one organisation to another, it's of the utmost importance to know the regulations and communicate with all collaborating parties to ensure that best practices are followed to the letter. But beyond that, linguistic validation is a good time to read between the lines, and look at areas outside the on-paper regulations that have the potential to raise red flags during regulatory approval.

One aspect of the linguistic validation process that requires careful planning and consideration is cognitive debriefing. ISPOR regulations for linguistic validation strongly recommend that the cognitive debriefing process involve patients suffering from the condition. In the majority of cases, this part of the process is the first time the instrument is seen by outside individuals who have little or no medical knowledge. The patients' answers to the questions are not statistically relevant during this phase, but the patients' reactions to the questions will help to determine how the instrument is presented during the actual trial phase – and how it is presented can have a major impact on the validity of your data and, therefore, the outcome of the study.

During this process, an in-country investigator presents the instrument to each patient or layman and notes response times, body language, and any misunderstandings associated with the language. It is important during this phase to pilot the instrument with a diverse group of participants, each of whom should represent a relevant cross-section of your study group (a variety of ages and education levels). It's preferable for companies to source in-country investigators and patients through an impartial third party, whether it is a capable language service provider (LSP) or a patient-sourcing company. Because of the expense and intricacies involved with sourcing patients, however, many pharmaceutical companies either source these patients themselves or don't use

It's not just the accuracy of the text being translated, but how a message is conveyed that is of critical importance to a successful cognitive debriefing. One should start by considering how each culture views clinical research in general and structure the cognitive debriefing accordingly. The content and graphic design should be customised to the desired target patient population.

patients at all. It is especially important that when they use their own in-country investigators, pharmaceutical companies pay attention to the delivery process and convey contingency plans in advance. In-country investigators should be given specific guidance concerning what directions, if any, they can give the participants and instructions for delivery. Also, pharmaceuticals should ensure that in-country investigators are following a standard protocol so that the participants have an equivalent experience.

It's not just the accuracy of the text being translated, but how a message is conveyed that is of critical importance to a successful cognitive debriefing. One should start by considering how each culture views clinical research in general and structure the cognitive debriefing accordingly. The content and graphic design should be customised to the desired target patient population. By being culturally aware and sensitive, the most appropriate recruitment materials can be created and, ultimately, a better overall result for the campaign achieved. Pharmaceutical enterprises know that language service providers have an excellent grasp of these cultural considerations, which is why pharma companies tend to look to them when they reach the linguistic validation phase of a clinical trial. But addressing these cultural issues at the onset can reap even greater rewards.

A HOLISTIC APPROACH TO CLINICAL TRIALS

While no part of the clinical trial process is simple, linguistic validation tends to be viewed as an especially complex and, therefore, delicate hurdle to overcome. It is, then, no surprise that many pharmaceuticals source the translation and management of linguistic validation to third-party providers who can execute translation and delivery, while adhering to ISPOR and government guidelines.

While linguistic validation (LV) is not strictly regulated at this time, the days of *ad hoc* translation of single documents generated during the drug development process are behind us, and most LSPs tend towards a more integral strategy of partnering with pharmaceuticals, understanding their business model, and functioning as an extension of their own operations. Through a comprehensive approach to language services, companies are not only able to ensure they are following the regulatory guidelines to the letter, but they can also save time and money.

Due to its delicate and precise nature, all translations during the LV stage must be done from scratch; however, for other parts of the clinical trial process, translation memory (TM) technology can help achieve cost savings and increased efficiencies. TM tools allow translators to leverage pre-existing translations that are mapped to source language. Any time that a source language phrase or sentence appears in the TM database, the linguist is given the option of accepting prior translations of that same content segment. This process greatly increases the consistency of translated material, speeds up delivery of final files, and helps reduce costs as charges for proofreading repeat text are much lower than those for translating new text.

The more translation processes are centralised, the greater the size of the translation memory. With each subsequent translation project, the likelihood of repeat text appearing increases. This is one of the reasons why it's advisable to think holistically about any translation requirements as they relate to all phases of drug development. From internal R&D documentation and patent applications to clinical trials material and even healthcare marketing efforts, the centralisation of translation efforts and use of translation memory can save hundreds of thousands of euros.

CONCLUSION

Though linguistic validation is a seemingly logical step in the clinical trial process to solicit the assistance and expertise of an LSP, many pharmaceuticals will save time and money by recruiting language and cultural help from the onset of the clinical trial. During the principal clinical stage, for example, pharmaceuticals amass a vast number of documents that must be translated with the requisite scientific and technical precision in order to be submitted to the relevant competent bodies. These first phases of the trial represent an unparalleled opportunity to establish relationships, protocols and preferred workflows. This groundwork will pave the way for more efficient translations and a high level of consistency from leveraging the same language talent throughout the trial. And these benefits can be applied to all of the company's translations, from internal communications to human resources and marketing materials. By consolidating all of their language services with one provider, pharmaceuticals essentially get the most value for their money – and a heightened level of accuracy to boot. ◆

The author can be contacted at jeker@transperfect.com