

No Longer Lost in TRANSLATION

Increased requirements, from both the regulatory and independent review board/ethics committees, have resulted in more information and documentation requiring translation.

DR. GAVIN LEONG
Criterium



The materials we translate in the patient recruitment department are given to patients to assist them with making a well-informed decision to both enter and remain engaged in a clinical trial.

NANCY DWORACZYK
Kendle



As drug development continues to become more of a global endeavor, it's more important than ever to ensure that documents, especially informed consent and other patient materials, are correctly translated into local languages to ensure the success of the trial. The increasing number of trials, as well as the need for treatment-naïve patients, is forcing more pharmaceutical companies to look outside the United States for sites and patients. According to clinicaltrials.gov, currently there are 93,782 ongoing trials in 173 countries.

The need for translation services is definitely growing because of the global nature of clinical trials, says Nancy Dworaczyk, associate director of patient recruitment at Kendle.

"Several years ago, trials were most commonly conducted in the United States, but over the years the number of patients available for studies has declined because of the competitive nature of trials and the increasing number of trials," she says. "This has forced pharmaceutical companies and CROs to go outside of the United States."

Chris Ellis, senior director, global project management and clinical operations, at SRA International, says there has always been a need for the accurate translation of study documents, but the requirements have become more stringent over time.

"Most regulatory and ethical committees require protocols written into the local language," he says. "Sites and investigators also need to have the same information translated, as well as any supporting materials."

The need for translation services is increasing primarily because of the increased access to clinical trials, which means many more people are

requesting additional information, says Gavin Leong, M.D., medical monitor/clinical operations manager, at Criterium.

"This could also prevent possible language, racial, and regional bias and give more representative participation of the population in the trial," he adds. "Most importantly, it conveys the information to the participants in the language they read and understand. This allows them to be more comfortable in making an informed decision about participating in a trial."

The ability to rapidly recruit suitable participants is eroding the boundaries around the globe, and the emerging markets of Eastern Europe, Asia, and Latin America are increasingly being tapped as potential sites. According to Thomson Center Watch, 20% to 30% of clinical trials are being conducted in developing regions.

But trials in emerging markets present challenges, language being one of them. In India, for example, there are 11 languages spoken by more than 25 million people each, with a 12th language spoken by just under that number.

Mr. Ellis says over the past two or three years, SRA has moved a lot of research into the central and eastern European countries, as well as some countries that were part of the old Soviet Union, where translation services are required.

Ms. Dworaczyk says for patient recruitment specifically, it is important that materials in the local language explain the details of the study to a patient so that informed consent can be obtained.

"It's important that patients have materials that are geared to their understanding and their level of literacy," she says. "We tailor how messages are written, the quantity of words, the verbiage, and the difficulty of the words to the patient population that we're dealing with."

Kendle translates its patient-facing materials for clinical trials, which are used to explain the study details to a patient; obtain informed con-

Top 10 Languages Around the World

Language	Estimated No. of Speakers
Mandarin Chinese	...1.05 billion
English510 million
Hindi490 million
Spanish420 million
Russian255 million
Arabic230 million
German229 million
Bengali215 million
Portuguese213 million
French130 million

Source: The Marketing Analysts. For more information, visit themarketinganalysts.com.

Experts on this topic

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sent; assist patients with future appointments; provide them with information if they experience an adverse experience; and educate them about their medical condition and provide links to support groups/advocacy groups.

Best Practices

Mr. Ellis says the biggest mistake companies make when translating documents is trying to cut corners to keep costs down. He suggests using professional translators.

"We don't attempt to do these translations ourselves," he says. "There are companies that provide trained translators who have experience in medical terms and who are native to the country and language that needs translating."

Mr. Ellis suggests getting a reference and auditing the translation service before working with a company.

"We review translation companies' standard operating procedures, their training procedures, their turnover, holiday cover, and verification services," he says. "We send them a simple one-page patient information leaflet and ask them to translate it into three or four key languages. We might ask for two easy lan-

guages, such as French and German, and two more complex languages, such as Russian or Bulgarian; then we have our local staff review those documents for accuracy."

Dr. Leong suggests that documents be back-translated by a different translator.

"The original English document and the back-translated document are then compared to ensure that they are as identical as possible, allowing for regional and cultural differences," he says. "Any differences are evaluated to ensure the meaning has not changed. The translated document is then reviewed by a person fluent in the translated language to see if it is compatible to the original version."

Ms. Dworaczyk says another important best practice is tracking document versions.

"We will have multiple layers of review, and even after a document is supposedly finalized often changes will come along," she says. "We're dealing with protocol amendments, various changes in drug formulation, or study duration variations." ♦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

ViewPoints

We asked our experts what best practices companies should consider when looking to overcome language and cultural barriers.



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Quality translation is a key element in the success of global clinical trials, and that involves more than just simple translation from a source language into a target language. The translated text must be culturally adapted in order to avoid being misconstrued. Linguistic and cultural issues can be overcome to a large extent with proper clinical trial management. Adequate translations must therefore be performed by experts who are native speakers, are familiar with the culture, and have a professional background in clinical research. Language service providers and CROs with first-hand experience in a specific country or region are best equipped to help address such linguistic or cultural barriers.

Language Connections is a full-service language service provider. For more information, visit languageconnections.com.



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An essential element of success when considering translation for global clinical trials lies in the planning stage. Too often, localization is an afterthought, so where possible, engage a language service provider before documents are finalized and materials have been selected. Make sure that the supplier has in place good quality processes to ensure that clinical documents are well translated and appropriate for the target audience. When looking to translate and linguistically validate PRO instruments, it is vital to work with a supplier that has in-depth knowledge of the PRO field of study, including the various guidelines and requirements as laid out by organizations such as ISPOR.

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