

# CASE STUDY: LIFE SCIENCES

## *Translation of Patient-Reported Outcomes into 40 Languages for 50-Country Drug Trial*

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### CLIENT PROFILE

Our client is a private, billion-dollar Japanese company specializing in several therapeutic areas, including psychiatric drugs.

### CLIENT CHALLENGE

As the number of clinical trials continues to grow outside of the U.S., instruments used to gather data directly from the patients, or Patient-Reported Outcomes (PROs), must be translated into the patient's native language. In order for an instrument to be used in international studies, it must address the same concepts in all languages to make it possible to pool data and compare results across countries. This is done through a series of steps involving multiple teams of translators, as well as focus groups for accuracy across languages, dialects and cultures. However, once the English version is translated into another language, the possibility of inconsistencies arises.

The client reached out to Welocalize Life Sciences to translate 10 patient instruments used to measure the effectiveness of the medication being tested into 40 languages for a 50-country drug trial. The client also wanted the translation validated through pilot testing on real people via focus groups in 40 languages in more than 20 countries.

### WELOCALIZE LIFE SCIENCES SOLUTIONS

In order to successfully pool data across the multinational clinical trials, Welocalize Life Sciences worked with multiple teams of local, native language translators, as well as focus groups, to ensure accuracy across languages, dialects and cultures. We conducted more than one forward translation of the instruments. These translations were then reconciled into a single forward translation using the best components of each. Another team then completed a back translation into English, which was then compared to the original source file. Based on these findings, mistakes or ambiguities were corrected. Then, the single language file was culturally adapted into the local dialects.

With so many linguistic differences and cultural nuances – even within the same trial country – it was crucial to validate trial documents for linguistic and cultural accuracy. To test the translation, or validate the accuracy of an instrument, Welocalize Life Sciences performed cognitive debriefing of the translation on real people. The focus group, which was run by a moderator, consisted of people across diverse economic, education and demographics to make up a general population for the testing.

*In order for an instrument to be used in international studies, it must address the same concepts in all languages in order to make it possible to pool data and compare results across countries. Welocalize provides linguistically and culturally accurate translations, which are critical components of pooling data across countries.*

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### FEATURES

- ✓ Translation and linguistic validation from English into over 40 languages, including Latin American Spanish, seven Indian and Filipino languages
- ✓ Client was able to successfully pool data across 50 countries

### BENEFITS

- ✓ Through focus groups, Welocalize Life Sciences uncovered areas of cognitive difficulties, grammatical mistakes or culturally inappropriate statements
- ✓ Rigorous processes meant accurate, on-time translations of PRO
- ✓ Culturally and economically relevant translations led to greater compliance by the patient and high quality content recorded by the patient during the trial

### FACTS

175 Languages  
1500+ Employees  
20+ Global Offices  
4th Largest US LSP\*  
7th Largest LSP worldwide\*

\*Source: Common Sense Advisory, 2016

### HEADQUARTERS

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### ABOUT WELOCALIZE LIFE SCIENCES

Welocalize Life Sciences provides specialized language solutions for highly regulated industries. Our solutions include industry expert localization and translation services for regulatory and compliance content, document translation, linguistic validation, interpreting, website and marketing localization, eLearning and multimedia services. Welocalize Life Sciences is an industry leader with proven translation and localization proficiency required for global clinical trials, pharmaceuticals, biotech companies, medical devices, healthcare brands, medical providers and government agencies.

Welocalize is ISO 9001:2015, ISO 17100:2015 and ISO 13485:2012 certified.

[lifesciences.welocalize.com](http://lifesciences.welocalize.com)

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LIFE SCIENCES

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OUR PURPOSE