



Three Best Practices for Clinical Trial Translation

Successful global clinical trials require early consideration of the costs, complexities, and risks of communications. Best practices for clinical trial translation ensure your global trials are efficient, cost-effective and successful in all markets.

The target market for conducting global clinical trials has changed significantly, moving beyond pharmaceutical early adopters to the mainstream marketplace. This shift has placed a heightened focus on the language challenges and complexity of running a global clinical trial.

Rapid expansion into diverse cultures and languages adds significant complexity to the clinical trial process. It changes the risk profile dramatically and cannot be overlooked. If economic models and risk scenarios are built for the trial but the data inputs do not include a true consideration of the cost, complexity and risk of translation quality, the trial's end goals will be jeopardized. The issue of language is as critical to the process as patient screening or any other trial planning element.

As a result of our work with global clinical trials, we've developed the following best practices to ensure a seamless process with the desired results.

01

Develop a Comprehensive Translation Strategy at the Outset

Plan for the complexities of language early in the clinical trial process. Do not assume that every bilingual or multilingual person can be a translator. Further, do not assume that someone who is very good at translating product documentation can make the transition to translating highly-sophisticated clinical trial terminology.

Instead, build in time to streamline the communications effort and secure a translation partner who has the scale to be your centralized resource for multi-geography patient locations and regulatory filings. Large-scale translation partners have the ability to scale quickly based on the project timelines and bring the required language resources to the project. They also have the ability to deliver clean, consistent data across languages.

02

Establish and Follow Standardized Processes

While the nuances of each step may vary, be sure to execute a complete translation process that includes:

- + Forward and back translations
- + A clinical review
- + Harmonization
- + Cognitive debriefing
- + Pilot testing
- + Finalization report

While standard translation projects will often go through a translation and then one subsequent review cycle, clinical trial translations add several critical steps to ensure the final translations are acceptable and ISPOR/ISOQOL compliant (validated translations). This is most notable in the translation of the PRO instrument. Much of the trial's data validity and subsequent analysis hinges on the patients' comprehension of PRO questions, how well their answers comply with those questions, and how effectively the material has been translated for analysis. The approach to translation affects the validity of the study, so it is important to have a complete and standardized process to ensure quality and reduce risk.

03

Optimize the Review Process to Shorten Review Cycles

The area that is most problematic in clinical trials is the translation review process. These reviews are often conducted by in-house staff, each with other full-time responsibilities. As a result, even though the translation is complete, the final review cycle can take as long as 8 to 11 weeks.

Critical to shortening this step is outsourcing the review to an independent resource. Typically, large-scale translation providers can assist by offering independent reviewers to conduct the language QA process. Keeping these resources separate from the translators ensures the objectivity of the QA effort.

There is no shortage of examples of how things can go wrong in translation in all industries; but it is much easier to alleviate these challenges in clinical trials if you plan for them. If the translation process becomes the bottleneck to launching the trial, this can have serious downstream effects, including lost revenue and the difference between a successful drug and a market miss.

Lionbridge Life Sciences welcomes the opportunity to explore the value of our Clinical Trial Translation solutions for your organization. We invite you to contact us for an initial discussion. <http://www.lionbridgelifesciences.com/contact/>