Lionbridge
LIFE SCIENCES

Expert
Language
Translation.
Global
Success.

Scaling to meet your translation needs

SOLUTIONS OVERVIEW

Best-in-Class Services for Patient Reported Outcomes in Global Clinical Trials

Effective use of language is critical to the clinical trial process, particularly as it relates to Patient Reported Outcomes (PROs). Data collected by PROs are increasingly accepted as primary endpoints of clinical trials in health research. It is essential, therefore, that data collected be accurate and reliable. Yet, this is only possible when patients are able to understand the questions asked and select response categories that represent their health status.

Many pharmaceutical companies and CROs believe their language partner has the cultural and clinical depth of knowledge and the protocols in place to fully comply with regulatory requirements surrounding PROs. This is often not the case.

A good way to evaluate your situation is to ask yourself the following…

- How certain are you that the information being collected about your patients for a particular disease state would meet regulatory requirements?
- Does your cognitive debriefing effort fall below regulatory body recommended best practices, leaving you open to interpretive risk and less than adequate data?
- What best practices are actually being followed? Are they, in fact, the best practices of regulators, or simply packaged as such?
- Would you be prepared to take the formulations of your scales to the regulating bodies?

With Lionbridge Life Sciences, you can be assured that our translation and linguistic validation methodologies are ISPOR compliant and based upon guidance from the FDA and EMA. In addition, the depth of our clinical expertise means we have access to disease-specific industry thought leaders to ensure that the content in your trial instruments is ideally presented for maximum data collection.

Using Lionbridge Life Sciences, which has the largest pool of expert in-country resources of any translation provider, is the most reliable way to ensure cultural relevance and comprehension of your instruments among your test subjects.

Linguistic Validation

Our process highlights include:

- Two forward translations
- Reconciliation
- Back translation of the reconciled forward translation
- Comparative review of the back translation to the source document
- Clinical review: Ensures translation decisions are medically sound across every language version
- Pilot testing and cognitive debriefing: Comprehensive interviews with in-country native speaking patients in the disease state, to test the interpretation of all translations, ensuring their clarity, intelligibility, appropriateness, and cultural relevance
- Multilingual harmonization: Assess consistency of translations and adaptations across all languages under test to guarantee best possible equivalence of construct value
- Finalization and certification

Lionbridge is currently working with some of the largest global clinical trials today; many with more than 5000 participants in more than 10 countries per trial.

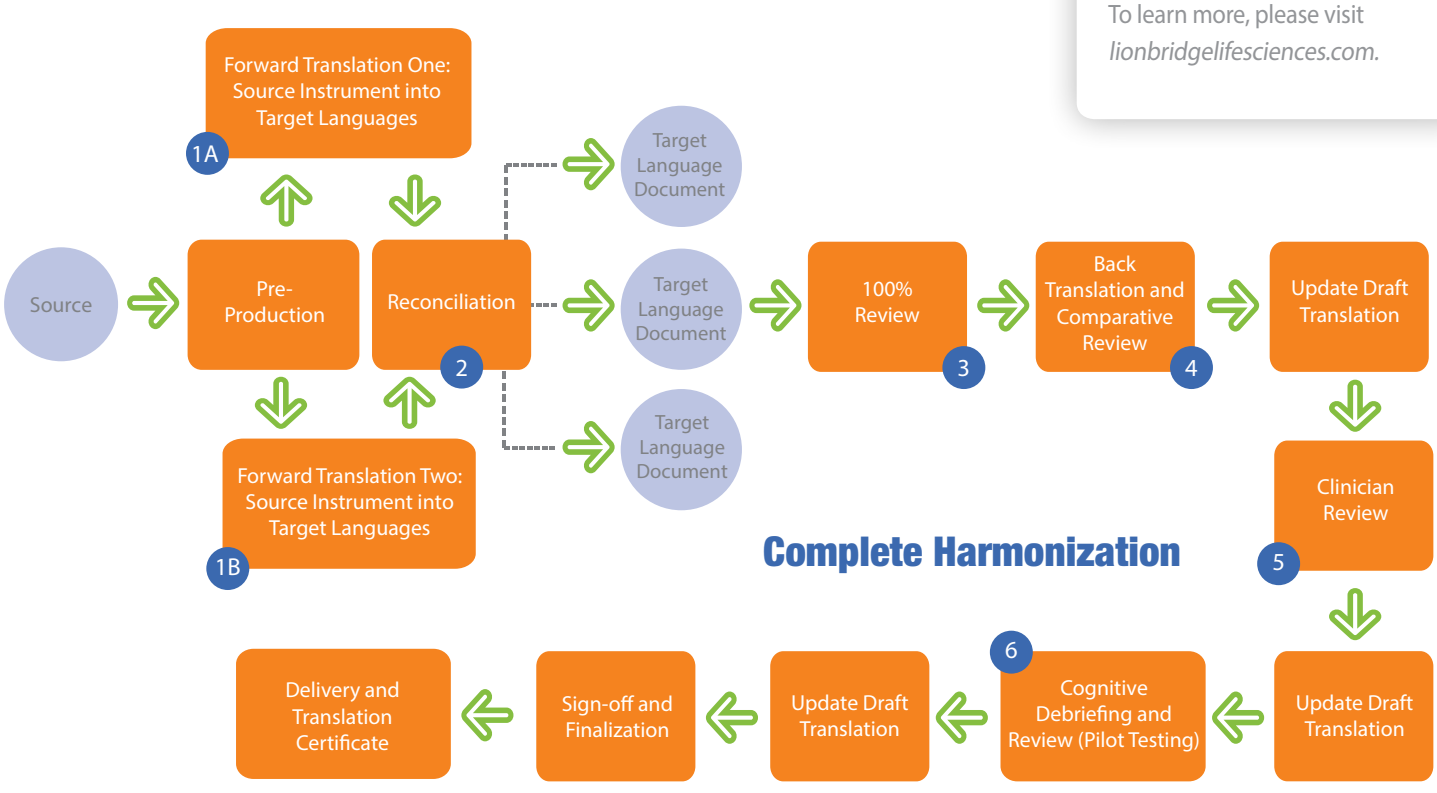
#1 ranked Language Service Provider by Common Sense Advisory Group

Translation Expertise:

- Five dedicated Life Sciences Centers of Excellence and clinical trial service teams across the globe, ISO (9001 and 13485) certified
- Highly-specialized, clinically-trained network of linguists, translators, and healthcare professionals with extensive experience in PROs and ePRO
- Process based on industry standards (ISO, EN 15038, SAE J2450 metrics, etc.) to deliver high-quality translations demanded by the Life Sciences industry
- Robust SOPs specific to clinical trial translations, including well-structured, ISPOR-compliant methodologies for linguistic validations, as well as conforming to PROMIS guidelines
- Cognitive debriefing performed with in-country patients in the disease state pursuant to FDA recommendations

Proven, Efficient Process

Our highly consultative, time-tested process incorporates a linguistic validation protocol that meets regulatory-defined best practices and yields significantly higher-quality results, giving our clients an edge in quality and time to market.



Clinical Trial Therapeutic Experience:

- Cardiovascular
- Dermatology
- Diabetes
- Endocrinology
- Gastroenterology
- Geriatrics
- Gynecology
- Immunology
- Oncology
- Psychiatry
- Pediatrics
- Rheumatology
- Urology

Work with the experts at Lionbridge Life Sciences for tested and trusted patient reported outcome requirements – the first time and every time. To learn more, please visit *lionbridgelifesciences.com.*