

"Lionbridge Life Sciences offered us the flexibility and scalability we needed to run an effective global clinical trial that produced very viable patient data."

- Leading CRO

Lionbridge Life Sciences therapeutic experience includes:

- Clinical trial materials and related filings
- Compliance and regulatory submissions
- Patient and clinician education materials
- Patient diaries and interpretations
- SmPCs and IFUs
- Patient reported outcomes

Linguistic Validation and Translation Services for Global Clinical Trials

Specialized Resources for High-Quality Deliverables and Rapid Turnaround Times

A critical aspect of global clinical trials is communication. Pharmaceutical companies must efficiently communicate with study participants who speak many different languages and represent a variety of different cultures and markets. A significant portion of the materials involved in a clinical trial need to be adapted for the target population.

Pharmaceutical companies and Contract Research Organizations (CROs) conducting global trials are seeking more efficient approaches to Linguistic Validation and Translation Services. In an industry that is guided by the principles of total quality and turnaround time, the smallest delay or a single translation error has immediate and resounding implications on an international clinical trial.

With some trials taking place in as many as 30 different markets, it is critical for translated instruments to be conceptually equivalent to the original content and to all of the other language versions. They must also be culturally relevant and acceptable to the target population within each country. The translation of clinical trial protocol demands a mastery of medical and pharmaceutical language. This requires that translators have a high degree of expertise in both linguistics and medical science and understand both the language of the end-user and the language of the trial. It also requires a sound approach to project management, ensuring that every aspect of a 30+ language translation project is well-managed and on-schedule.

Specialized Knowledge and Skills

Linguistic Validation and Translation Services for Global Clinical trials is a highly-specialized business at Lionbridge. We have dedicated clinical trial service teams operating in 26 countries around the world, helping pharmaceutical companies and CROs reduce their translation turnaround times by 50% or more, and ensuring simultaneous roll-out of clinical trial materials across many geographies and languages.

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. We also support some of the largest global CROs.

Working with Lionbridge, these companies gain access to a highly-specialized network of linguists and translators who have extensive medical and scientific training and experience. Our centralized approach to translation, coupled with our global project management methodology, ensures consistency and quality across languages, while reducing the total time it takes to adapt and translate clinical trial support materials.

Bringing a drug to market can cost as much as \$500 million. Every delay in releasing the drug can mean hundreds of thousands of dollars in lost revenue. Lionbridge recognizes that the pressure to move quickly during the translation phase is intense, and our teams work to alleviate this pressure.

Global Scale & High Quality Services

Lionbridge has the scale to be your centralized translation partner for all of your global patient trials. With thousands of project managers, linguists, translators, publishers, programmers, and engineers operating worldwide, the Lionbridge team is unmatched in terms of depth, breadth, and experience. Our ability to simultaneously support your efforts in 20, 30, 40, or more markets, without negatively impacting your timeline, is what sets us apart. We can ramp up or down very quickly, across many geographies, as your trial needs evolve. We also have the ability to deliver clean, consistent data across every language. Working closely with you, we ensure that all of your materials are absolutely accurate and of the highest quality.

The goal of any linguistic validation program is to ensure that all of the data used to interpret the trial are clean and conceptually equivalent to the source instrument. Lionbridge ensures this through a rigorous process that includes:

- **Clinical Translation Services:** High quality and simultaneous forward, and back translation by specialized resources, in over 60 languages.
- **100% Clinical Review:** Ensures the consistency of translation decisions across every language version by comparing translations item by item.
- **Cultural and Linguistic Analysis:** Determine key factors in each locale that may impact an instrument's effectiveness, and ensure conceptual equivalence.
- **Pilot Testing and Cognitive Debriefing:** Interviewing native speaking trial subjects 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.
- **Desktop Publishing:** Final publishing of reports and materials to be used in the trial.

Lionbridge Value

With operations in 26 countries, Lionbridge has the scalability and technical infrastructure to be your centralized translation partner for multi-geography clinical trials. Lionbridge employs a flexible, but well-structured methodology that helps organizations enjoy the quality of in-country translations with the efficiency of a unified process. Our approach leverages a robust technology platform to facilitate simultaneous translation in all languages, using the largest network of certified Clinical translators in the world.

Our trusted teams of project managers, translators, publishers, and QA professionals have deep, hands-on experience adapting clinical trial content for global markets. They also have an excellent track record in delivering projects on time and with high quality, lowering your operational risk.

Lionbridge Life Sciences is the leading provider of language services to medical device developers, pharmaceutical companies, and CROs. We specialize in high-quality translation, linguistic validation, and interpretation services in over 150 languages. Lionbridge clients benefit from our highly specialized network of medically trained linguists, operating across 26 countries.

Sample Lionbridge CT Program Experience:

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

Lionbridge Fast Facts

- Support for more than 150 languages
- Solution centers in 26 countries
- ISO 13485, 9001:2000, and EN 15038 certified operations
- Over 4,600 employees supported by thousands of translation resources
- Lionbridge project managers, engineers, content developers, and linguistic experts work with a virtual organization of 10,000 independent linguists, all certified in specific domains such as clinical trials and pharmaceuticals

→ To find the Lionbridge office nearest you, visit www.lionbridge.com