



Choosing the right medical translation provider can help in-house regulatory and clinical departments and contract research organisations support strategic growth while controlling costs and minimising risk. In this practical guide to hiring a translation agency, we discuss eight key steps to take when choosing a vendor, ranging from assessing domain knowledge to managing liability and security.

It is a familiar scenario: the portfolio manager or project manager receives a call from an internal business unit or subsidiary. Management has approved a new trial concerning multiple sites and countries that they need the start-up team to manage. Translation will be required and the budget and timeline are limited. The clinical team sizes up their options and calls their trusted sites. Do they have a local contact they could use, and how much will it cost? Will the study follow the new CTR 536/2014 requirements and be submitted in the Clinical Trials Information System (CTIS)? Have all the necessary patents been requested?

Such a scenario can cause a sharp intake of breath for even those clinical departments with a well-managed network of local partners in place. The local site may not have the necessary skills to relay the trial documentation in plain language for instance. Alternatively, it may be cost prohibitive or unfeasible to use local sites to perform translations as local sites may still be charging by the hour. Furthermore, ‘translation’ may be far down the priority list in comparison with other activities required during the study.

There can be issues of consistency or quality too. Where work is scheduled as a one-off and under time or budget constraints, how can you be sure that the translations will be understood by trial subjects or accepted by regulators?

Clinical documents might not be scrutinised until they are needed most – for example, during the ICF review and signature stage. If quality is not assured early, there is a real risk that the sponsor will pay later either through additional costs, delays to the clinical trial or a risky misunderstanding by a trial subject.

When we talk about translating plain language summaries (PLS), the use of inadequate wording or approaches can also have



drastic consequences. Trial subjects and carers must understand the study requirements, the due diligence required to participate or the reasons why the drug may not have the desired effect. Lack of understanding may drive subjects away from participating in the study.

5 Reasons Clinical Documents Require Professional Translation Support



1. Domain Knowledge

Sourcing translations for global clinical trials starts with recruiting linguists with knowledge of the relevant market, therapeutic area, document types, audience and linguistic preferences. Oftentimes, clinical texts can be highly medical and these should not be entrusted to providers without domain-specific experience. Domain-experienced LSPs should be aware of, and help you adhere to, essential legislation like the EU Clinical Trial Regulation.



2. Local Knowledge

Established LSPs show awareness of local linguistic nuance, familiarity with diverse document types, appropriate register (scientific or lay), as well as the need for formal certification, legalisation or notarisation.



3. Certifications of Accuracy

Clinical documents require certification that translations have been accurately performed. Certification gives those parties that rely on the documents the added confidence that the translation has met the agreed standard.



4. The Right Language

To effectively manage global clinical trials, sponsors and CROs insist upon a diverse team of qualified linguists. Also essential are agile and ISO-audited recruitment processes allowing to scale at speed according to changing linguistic requirements.



5. Risk Mitigation

A company’s reputation can hinge on the quality of their translated materials. Errors and inaccuracies can increase regulatory hurdles, undermine a company’s strategy or cause misunderstanding among trial subjects. In addition, having to find and correct errors introduces additional cost and takes time, meaning that both profit margins and schedules are negatively affected.

Providing Consistency Across All Operations

Working with a Language Service Provider (LSP) that provides translations across all relevant medical fields, from clinical and pharmacovigilance to product registration and marketing helps to streamline the management of translation tasks and build consistency across all translated materials.

As sponsors and CROs know all too well, translating clinical texts is not the same as translating standard documents or training materials. The influence of non-specialist language coupled with insufficient knowledge of the therapeutic area introduces the risk of confusion among trial subjects or unwanted regulatory roadblocks.

As sponsors typically give each department the authority to choose their preferred language service providers, it's common to rely on one LSP for clinical trials, another for corporate translations, another for marketing authorisation applications and another for patents, for example. While the technical expertise of the different providers is crucial in such scenarios, so too is the need to ensure security and quality across translations, and to set clear deadlines.

Using multiple translation suppliers can be not only time-consuming and inefficient but also risks undermining efforts to achieve a consistent quality standard in a cost-effective manner.

LSPs, in contrast, prioritise translation consistency and quality. They combine in-house production management with global freelance linguistic talent to offer a single trusted resource for language services, adhering to tight timeframes and pre-set budgets. It is for these reasons that the emerging best practice among successful CROs is to unify traditionally disparate language requirements under one or two high-performing LSP.

Choosing the Right Provider: A Step-by-Step Guide

Today's sponsors and CROs operate in an increasingly global marketplace. Within the Life Sciences especially there is a need for compliant and accurate translations no matter the target language. As the need for translation grows, so too do the risks and potential costs of getting it wrong. Avoid the potential pitfalls with our step-by-step guide to choosing a provider.

Step One: Identify Your Needs

It may seem obvious, but if your documentation is specific to the domain of clinical research then the LSP must have proven experience with the clinical trial process and a track record of accurately translating the relevant documentation.

An experienced LSP will not only help you identify and assess the documentation you need to translate, but also help you estimate a translation budget for your entire clinical trial.

Step Two: Chart the Workflow

Time is of the essence when setting up and recruiting subjects for a clinical trial or responding to adverse event reports. Understanding the translation requirements and outlining a tailored, semi-automated workflow early in the process is crucial. The agreed workflow can include back translation, linguistic validation, certification and also allow time for all of the necessary review and approval processes.

Step Three: Match Those Requirements with Providers

Does your LSP have the necessary domain knowledge, languages, and turnaround times that you and your clients need?

Not all LSPs specialise in Life Science translations, so it may be that your existing vendor struggles to provide end-to-end support across your entire industry. Rather than finding this out through quality issues, be open about the needs of all departments and seek out an LSP who is competent at unifying them.

Accurately translating your company's message (whether clinical, regulatory, advertising or training, etc.) requires in-depth knowledge specific to each domain. For example, to translate an informed consent form (ICF) or a clinical trial summary, sponsors require a translator to be familiar with the therapeutic area as well as the language and culture of the region in which the trial is taking place.

As well as the idiosyncrasies of local languages, your chosen translation vendor needs awareness of specific glossaries such as medDRA where applicable. This will impact terminology choices and understanding by the target reader. Equally important is knowledge of any technical or scientific field or discipline covered by the text.

It is also appropriate and advisable to request references from any agency you consider working with. Do not hesitate to ask for references in your same field to ensure that the vendor has relevant previous experience.

Step Four: Consider Your Security, Confidentiality, and Governance Requirements

No matter the content of your documents, your translation vendor should always have processes in place to ensure the security and protection of your confidential information both in transit and within their systems. Ideally, your chosen vendor should possess ISO certification and/or SOC 2 Type II security certificates. Be sure to discuss these issues in advance of sending content to your vendor.

Step Five: Make Sure You're Covered

Initiate conversations about diverse translation requirements in your vendor selection process. Your vendor should carry public liability insurance at levels commensurate with the financial penalties that are commonplace in your area of specialisation. Request proof of coverage to ensure that you are protected against translation mistakes, negligence, and data breaches.

Step Six: Manage Costs

No one wants to deal with hidden charges and unexpected costs. Professional LSPs will always provide complimentary quotes that clearly detail all costs, often itemised by language. Any changes to the quoted costs should be communicated to you by your project manager for approval in advance of being added to an invoice.

Step Seven: Run a Test Translation

If time allows, run a test translation project with the providers you are considering. This will allow you to compare costs, turnaround times, and customer service across all of your potential vendors. Most LSPs will complete small sample translations (of 500 words or less) for free, but may charge for larger tests. If your budget allows, it is best to request test translations using at least 2,500-5,000 words of source content. This will give you the best sense of whether a vendor can meet your needs.

Step Eight: Extend the Partnership

Once you have successfully completed a test translation and selected a vendor, consider unifying the requirements of other teams in your company in order to benefit from synergies across



departments. For example, BIG Language Solutions utilises various tools that help ensure consistency within documents and across multiple related projects by capturing and cataloging frequently used, specialised words and phrases that may be accessed during translation. BIG Language Solutions automates aspects of its workflow management to expedite the translation process where possible and deliver high quality translations in a timely fashion.

Why Hire a Translation Agency?

While many businesses operate globally, sometimes it can be hard to locate and enrol trial subjects across multiple sites/countries. Composed of various regulations and cultural perspectives, international regulatory systems are made up of a patchwork of different legislations, regulations, and directives, all with diverse and often inconsistent procedures, timeframes, and costs.

For in-house clinical and regulatory affairs departments to navigate this global landscape requires project management and language talent operating locally.

Traditionally, in-house teams have had no choice but to build a network of external advisors to meet their ever-changing needs. Meanwhile, language services providers have invested heavily in processes and technology to minimise cost and timelines without negatively impacting quality.

Outsourcing life science translations to a professional translation agency with local presence thus offers a quicker, more consistent, and more cost-conscious alternative to utilising unqualified, unreliable resources.

Global Reach, Local Expertise

BIG Language Solutions supports sponsors and CROs with fulfilling a wide range of translation requirements across diverse practice areas. Our expertise spans a wide range of disciplines in over 200 languages, and guarantees you the translation support you need to successfully operate global clinical trials.

Security First

We take a 360-degree approach to the translation process, looking at the bigger picture to extend security beyond our internal platform so that all touchpoints – people, processes, and technology – are fully secure. Our entire translation approach and IT infrastructure

are compliant with ISO standards 9001, 17001, and 27001 for quality, impartiality, and IT security, and we are SOC 2 Type II audited.

A Trusted Methodology

We follow a three-step quality process for every translation that we deliver. Our process ensures we deliver authoritative and accurate translations that support your success and help you mitigate unnecessary risk:

1. Expert Translation Done by a Qualified Professional

Each translation begins with an experienced linguist with an advanced degree in the subject matter. We require all linguists to pass a robust proficiency test that is overseen by our Medical Director who is a physician and professional translator. Less than 6% of candidates pass this initial stage. Those who do must complete evaluation to allow us to further assess their background, translation proficiency and industry expertise.

2. Independent Reviews

Unless otherwise agreed, every medical translation is revised by a second specialist translator.

3. Final Quality Assurance Review & Project Requirements Evaluation

Finally, QC checks are performed against your project brief and then a dedicated project manager packages and delivers the translation in accordance with your specific instructions.

DWL

DWL, A BIG Language Solutions Company is a global leader in medical translation services, providing specialised services across more than 300 languages. Drawing on 50+ years of experience, our united team of medical translation specialists provides prompt, secure, and cost-effective solutions to global pharmaceutical companies, CROs, universities, medical device companies and regulatory consultancies. Whether we're supporting global clinical trials, marketing authorisation applications or device registrations, our stringent quality assurance protocols ensure commercially sensitive data and documents are safeguarded and translated to the very highest standard. Contact us to discuss your medical translation needs.