



Improving the Outcome of Translations in Clinical Studies

With the advent of increased globalisation of clinical trials, pharmaceutical, medical device and biotech companies, often via their CROs, have adopted greater reliance on outsourced translations.

Within the clinical trials environment, translation projects account for a key expenditure a drug developer or clinical trial runner must make. Translations have become an essential link in the chain of development when successfully launching global products. For any product that is propelled onto the global life-science stage, the pathway invariably includes conducting clinical study translations which must meet stringent local requirements in all of the countries where the clinical trial is conducted. Following large investment in the clinical trial process, the prime concern for many life-science companies is the speed of delivering a product to market – and how to balance timelines, costs and quality to reach that goal. In this article, we analyse these and other powerful factors involved in producing the best possible translations and offer suggestions for improving their outcome.

Making the Right Choice of Translation Vendors

Company study start-up teams are the usual key users and beneficiaries of clinical trial translations services. These teams often have vital tasks in managing the core activities needed to prepare a strictly regulated clinical trial, often without resources to translate documents themselves or spend significant time on reviewing translations. Therefore, they require the support of a trustworthy translation vendor in order to handle the translation of their clinical documents. Within an international organisation (like most pharmaceutical companies and CROs), a global vendor management team is usually responsible for the selection of translation vendors, as well as vendors for various other business categories. The choice of a vendor should be complementary to the business needs of an organisation and every effort made to regularly assess and review the current choice of vendors to ensure they still fit the company structure and best working practices, and meet local and global requirements.

Talking to Your Stakeholders

Many vendor management teams find themselves in an increasingly tricky situation when it comes to translations. Alongside identifying new outsourcing solutions as well as the multitude of existing vendors of various kinds, with many offering highly complex scientific services, the time and resource for review of translation vendors will be limited. Selection of translation vendors may inadvertently be considered as low priority when compared with more well-recognised tasks such as the selection of patient recruitment support, CRO selection and genetic testing laboratories, for example. This approach is quickly changing, with vendor managers recognising the importance of translation

vendor selection. The impact of making the wrong choices are remarkable: delays in translations, or the need for intensive in-house work to salvage a low-quality translation that can lead to submission deadlines being missed, not to mention the costs of having submissions rejected by ethics committees and IRBs due to low translation quality.

It is pivotal for those responsible for managing vendors to discuss requirements and canvass opinion with the key stakeholders for translation projects – in this case the clinical study start-up teams – to increase the chances of a successful collaboration. Increased understanding of the challenges faced by the core teams and the requirements they have from their vendors can then be reflected accurately in the correct vendor choice being made.

Finding the Perfect Fit

It can be challenging to find one perfect translation vendor; in many cases such a utopia may not even be realistic or possible. What works for one organisation's needs, may not work for another. Specific challenges mean that a translation provider can demonstrate great proficiency in some tasks but may fall short on others. Many companies continue to opt for the largest translation vendors in the market, wishing to minimise risk of choosing another vendor, even though it may bring real benefit and efficiencies.

It is increasingly common for companies to select multiple vendors who offer a wide range of specialist help in key areas or specific geographic regions.

Building business relationships with several key translation vendors can work exceedingly well by reaping the rewards of improved regional support, faster timelines, higher quality and reduction of costs. A client may select a handful of global vendors to serve their needs but also enlist the support of several local vendors who can provide expert regional support in various parts of the world.

Regardless of which end of the spectrum, an organisation will need to have in place at least one go-to vendor that demonstrates a deep understanding and an eagerness to support their translations. Establishing a successful collaboration between life-science company and translation vendor will undoubtedly take time and investment to ensure the correct choice is made. Here, we can start to explore some further considerations.

Going Clinical

With an array of translation companies now specialising solely in translations for clinical trials, the search for the perfect vendor has become an easier task. These life-science dedicated translation vendors employ subject-matter experts, translators with a multitude of clinical trial experience and who themselves are native speakers with a great understanding of medical terminology. It is

less challenging to seek out translation vendors who specialise in clinical, regulatory, safety translations and international product marketing – many of whom can offer great insight and revolutionary case studies of how they can contribute to the successful processes for the golden triangle of: timelines, costs and quality.

Translation Vendors who Relish the Challenge

In an environment where there can be significant challenges such as urgent and complex multilingual projects or trials where translations are required in very rare languages, there are growing numbers of vendors that focus on meeting this very challenge. Such dedicated translation vendors achieve this in part by building a solid framework of expert translators in each and every country around the globe. These highly skilled translators are able to rapidly respond to the requirements of those managing and conducting a multinational trial. Creating a network of super-translators with key life- science skills, professional healthcare qualifications and clinical translation experience offers a ready-made team able to respond without delay, ensuring an agreed project gets off to the best possible start. Additionally, a new wave of translation vendors have chosen to apply fresh thinking that allows them to take on challenges by promoting a drive for a more service-orientated approach. What may have seemed like an impossible request, which some traditional vendors would have turned down or overpriced, can now be managed effectively and delivered through the drive to enhance customer satisfaction. By creating a modernised and flexible work environment with a prioritised service mentality, these agile translation companies are willing to take the extra step for each and every client. Many of these will offer solutions for more complex projects, allowing the studies to move ahead quickly.

The Risk and Rewards of Change

It can be a daunting prospect for those overseeing clinical trial translations to consider moving to a new supplier or even start to include a new entity in a raft of preferred vendors. The reward for time spent reviewing new or additional options can be seen in improved vendor performance: creation of new vendor candidates who demonstrate a fresh or innovative approach, and the acquisition of optimised processes that deliver cost savings driven by these efficiencies. There can be many such rewards waiting for those who actively review and select the best vendors, and do not necessarily make the obvious choice. Look for the vendors who demonstrate great service alongside their expertise of delivering translations on a global platform, and don't limit yourself only to the most well-known or most popular vendors.

Response and Delivery Timelines

Every translation company understands that in order to move projects ahead without delay, it must respond and deliver in a timely manner. Critical to this success is being able to respond to new requests for translation within a few short hours, not days – allowing the translation to be approved and initiated during the same day. Many forward-thinking and agile translation vendors now see this as a part of their key differentiators – an offering that will appeal to client project teams. The final delivery of the translation itself also has to be absolutely reliable. In today's competitive market, the best translation partners will not want to let you down and will pride themselves on their delivery track record. Project decisions are regularly made on the premise that translations are delivered on or before the allotted time. This is especially the case where regulatory submissions are made to local authorities and include the translated document into the local language. Delays or issues resulting from late or poor-quality translations can delay the clinical study by months if project deadlines are missed. Working with a translation partner that can deliver reliably should always be a priority.

Pricing – All That It Seems?

By their very nature, many translation companies operate differently on pricing. It can often be confusing to make comparisons – not everyone operates the same pricing policy. Some agencies will offer rates that include all aspects of conducting a translation – typically a rate per word that includes the type of QC process, certification, project management and inbuilt urgency cover.

Other agencies may charge generally per page, for some additional services or if rush timelines are required, by applying surcharges or premiums. It is imperative to agree an accurate and final cost before moving forward with the project, simply to ascertain if there are additional costs to be incurred.

It is recommended that the client company should also have their own definition and terminology in place for the required translation process before contacting vendors for pricing during the vendor selection process. The reason is that translation vendors often offer different processes with ever-changing names: translation and proofreading, translation and verification, translation and editing and various others.

The ISO 17100:2015 standard sets out the recommended translation processes very clearly together with the relevant naming conventions. If translation vendors are required to adopt and use the same terminology as the standard, it would enable an accurate review of pricing.

Counting the Cost of Internal Client Review

Once a document is translated by its translation partner, many clients now opt to have the translation verified by a second independent translator and in doing so, routinely also outsource this full review step. This is also the recommended process in translation standards such as the ISO 17100:2015.

Translation, review and revision is the standard process recognised by the clinical trial industry. The document is translated by the first translator, which is then followed by a full QC review of the translation versus the source document, performed by a second translator. It is universally recommended for clinical trial documents that are intended for investigators, patients and ethics committees. Outsourced verification is useful if there is no such available QC step in-house. It also allows the whole project to be outsourced and managed to include all steps and end-to-end delivery.

Reducing internal client time spent reviewing translations has shown to significantly reduce translation costs when such a verification stage is managed by an expert reviewer, who is well versed in the subject matter and clinical trial process.

For clients who opt to review translations in-house, there should be recognition and analysis of the cost of internal quality review. Valuable time can be spent by various client teams reviewing these translations, normally adding significantly to the overall cost. In-house review and associated costs are not usually accounted for as translation costs but will impact the client in far-reaching ways, including diverting the teams from other important and pressing study tasks.

Setting the Bar High on Quality

Both vendor and client will undoubtedly have high expectations of quality, since a great level of accuracy would ensure acceptance for the documentation for its intended purpose. Before the translation even begins, it is vital to agree what is



meant by a high level of quality, what the expectations will be of the translation and how it will be ultimately used. Will the organisation require an entirely exact and literal translation requiring supreme accuracy or alternatively, aim to produce a more fluent and straightforward text for the end-user – whether that be a patient, investigator or other healthcare-related role?

Adapting the Focus

Fortunately, translation vendors who work according to ISO9001:2015 and ISO 17100:2015 and EN15038:2006 accreditation, utilise translators who have the ability to adapt the focus of the translation to achieve a balance between communicating the exact phrase and making the translated materials more simplified for the intended end-user. Translation of a phrase may not necessarily be straightforward or a simple direct translation – it requires great skill to ensure the translation is accurate and fluent. There may be some element of stylistic choices delivered and this can vary from one expert translator to another. Over the course of a collaboration, many translation providers offer their clients the opportunity to select a preferred set of translators. These preferred translators will have demonstrated that they consistently deliver a translation which sets the correct tone, utilising the most appropriate scientific terminology whilst adopting the correct stylistic phrases that the client would expect. A great translator team will know the difference and take initial guidance from the core project team in preparation.

When Things Go Wrong

The real test of credentials of any translation provider will be when the unexpected happens – feedback is received that a translation falls short of client expectations. Especially at the start of a collaboration, it is often a time when both company and vendor work together on common shared goals, only to find out that they had more to learn about processes or expectations than they had first thought. It can be a time of learning for both client and translation provider – a time when there has been a steep learning curve on both sides. If a client has specific criteria and particular preferences, it may only become clear following review of the first set of delivered translations.

Given the right framework, it can be an opportunity for the client project team to reflect and refine requirements, and also allow a chance to educate the translators on sponsor requirements to deliver improved translations in the future. Delivery of the translation should certainly not be considered as the end of the service, but an opportunity to follow up, to assist with any update

required or to handle more pressing client feedback. Support throughout the life-cycle of a project builds a successful and trusted collaboration, increasing the value of the partnership over the long term.

Going the Extra Mile?

There are many ways in which the translation vendor can support you over and above providing a good quality requested translation, one within budget and one that is delivered on or before time. A key differentiator that sets translation providers apart can be shown in the willingness of a vendor to improve processes and drive efficiencies within the procedures. Vendors can also demonstrate how well they can adapt to changing client requirements, show flexibility and offer solutions for projects which may first appear complex. The right vendor will have vast experience of routine clinical projects but also have expertise in managing translations for studies that have challenged them to seek new and better ways of handling projects.

Moving Forward

The world of managing clinical trials is constantly evolving in a fast-paced environment. It is the intention of this article to reflect and consider the range of options for managing translations that will provide an optimal outcome for the clinical study. It is hoped to be beneficial for those who work in the clinical study environment, by highlighting the important factors that may facilitate further discussion and lead to the right choices being made. Translations are an essential part of the clinical development of a global product and with due care and consideration, will promote a successful product launch on a global scale.

Val Thorpe

Val Thorpe is Business Development Director at Transcom. Following a degree in genetics and subsequent roles within the NHS, CRO, pharmaceutical and medical device industries, she joined Transcom four years ago. Supporting translations for global pharmaceuticals and CROs, Val is focused on managing Transcom's Business Development function by developing key strategies for moving Transcom into new translation markets around the globe.



Email: valerie@tran-s.com