Q&A: 5 questions (and answers) on mastering translations in clinical trials

INTERVIEW WITH STEVE ELLISON, DIRECTOR OF CLINICAL TRIALS, LOFTWARE

Loftware™

Introduction

Labeling can be a major bottleneck in clinical trial supply chains, with delays potentially halting, or even in extreme cases collapsing entire studies. Managing country-specific labels for multi-national and multi-region trials is particularly complex and time-consuming, requiring accurate translation and compliance with local regulations. Without integrated systems, this task becomes labor-intensive and more difficult as trials grow in complexity and geographic scope.

Using multi-page booklets complicates labeling further, as each booklet combines multiple single-panel labels. Designing, populating, approving, and printing of these booklets can take upwards of 16 weeks, especially if countries are added late to address patient recruitment issues. Agile trial protocols add another layer of difficulty, necessitating on-demand production of materials to reflect up-to-date patient information.

In recent years, we have seen that fast, cost-effective trials are possible without compromising patient safety by embracing automation. This has increased the demand for accelerated clinical trial processes to deliver treatments to patients more quickly and improve overall experience. Sponsors and outsourcing partners are focusing on automating and streamlining the clinical supply chain to enhance efficiency and maximize return on investment before patent expiration.

This Q&A explores the complexities of translating clinical trial labels and identifies best practices and technologies that support consistency, compliance, and speed.

1

What are the key challenges of translation management?

A clinical trial label or multi-page booklet label contains various elements that must be managed for country-specifics, including sponsor names, trial codes, subject IDs, expiry dates, regulatory phrases, dosage details, administration routes, batch numbers, storage conditions, and return instructions. When creating labels for a clinical trial, it is common practice to create a “master label” in English from which country-specific labels are derived; translations of the master-level phrases need to be sourced before the localized labels can be created and sent for approval.

There are instances where a booklet label may be required even if the trial is conducted within a single country. For example, some countries have multiple official languages and numerous regional dialects, such as India, which plays an increasing role in clinical research. Each of these languages and dialects needs to be accounted for in labeling to ensure patient adherence and safety throughout each study.

In addition to ensuring that label content is correctly translated, organizations need to maintain compliance with other local and regional regulations, which could dictate the use of specific fonts or symbols. Despite most national regulators setting regulations based on US or EU standards, there are still numerous country-specific requirements, even for EU member states. It is a challenge to ensure that label designs comply with all regulations for the many different territories covered by a multi-national trial.

With general industry emphasis on speed of delivery, there is now an increased likelihood that target countries participating in the trial will change at short notice due to the availability of eligible subjects. Organizations need to be able to quickly source translations for label content and ensure that their label template design adheres to local regulations.

2

How do I manage a GXP-compliant phrase library?

Phrase libraries allow organizations to safely recycle content, providing a repository of approved translated master-level phrases that can be used without reference to an external translation house and repeating lengthy internal approval processes every time a phrase is used. This method can effectively save time and reduce costs without having an impact on safety.

All the “approved phrases” and “sets of phrases” should be managed and stored independently of specific trial information and the platform should offer tools to help language experts monitor the impact of proposed and actioned changes to phrases.

The library allows for more effective standardization of phrases across different studies. Most phrases can be correctly expressed in a variety of ways, and while technically correct, inconsistent phrasing is frowned upon by regulators due to the potential for patient confusion and health risk.

Phrases should be stored as Unicode with a specification for the approved font, point size, spacing, kerning etc. This ensures that phrases are used in the format that they were originally approved, ensuring legibility.

3

What should I look for in a translation management system?

For efficient GxP-compliant translation management, any software-based system must involve:

- Robust security features including granular access permissions
- Detailed user activity logs
- Version control management
- Import and export functions for source phrases
- Translation source language designation
- Impact analysis tools to better understand cause and effect of any change

In addition, there are several quality-of-life features that are highly desirable. These account for the various approaches to managing language data, offering flexibility to the user. For example, it is helpful if a solution provides support for:

- Central administration
- Trial-specific phrase sets
- Grouped phrases (e.g., dosage phrases)
- Ability to filter languages to those required for a specific trial

4

Could universal phrase packs be the future?

It has been argued that the industry could create a common phrase pack with translated master-level phrases like 'Keep out of reach of children,' ensuring consistency across studies. This pack could form the base of an organization's broader phrase library and include images and icons.

This approach mirrors other industries such as the medical device sector using an ISO standard symbol library, and the chemical sector using Global Harmonization Standard (GHS) for transporting hazardous materials in Europe, with standardized risk phrases and pictograms supported by commercial phrase packs.

5

What are the potential pitfalls in translation management?

Using a manual system or a phrase library solution that is not seamlessly integrated into the labeling workflow poses significant risks. Many organizations currently depend on Word or Excel documents or outdated custom software solutions that function separately from the labeling solution. Organizations that utilize translation management systems independent of their labeling workflow frequently face multiple issues of which I will dig into further.

First, **manual keying**. The label creation process involves users moving information between different systems by copying and pasting or retyping. This method can be time-consuming and may introduce errors, as manual entry processes are prone to mistakes. Any undetected transposition errors may cause delays or potentially invalidate the results of a trial.

Second, **lack of consistency**. Global regulators stress the need for consistent information about Investigational Medicinal Products (IMPs) for patients. Consistent phrasing during trials reduces patient confusion. An automated workflow is key to ensuring approved master-level phrases are used across all patient-facing materials.

Third, **spot subtleties**. Manual processes are subject to human error; retyping and editing can introduce subtle variations in the text, such as misspellings, truncation, or poor transposition, potentially altering the meaning of a phrase. Examples can be:

- Formatting changes may occur when copying and pasting information between different systems, especially around page breaks, line breaks, and word wrapping text
- Changes in pictographic languages, such as Chinese, can be difficult to identify if the user is not familiar with the character set
- Conventions that govern the use of plurals in English are not always applicable in other languages, and sometimes different plural forms of the same phrase are used, depending on the context

Fourth, **local revisions**. In the absence of a centralized and automated approved phrase library, teams and individuals may interpret information differently. Locally managed spreadsheets or other systems are susceptible to changes based on individual interpretations and preferences.

Finally, **auditing challenges**. The absence of a centralized electronic audit log can result in delays with audit requests, and when using a paper-based system, losing a single document could disrupt a trial or lead to the withdrawal of a product from the market. Additionally, paper approval processes often involve re-scanning proofs after each wet ink signature is obtained. Every scan reduces the quality of the image, making it challenging to read some elements of the label, and responsible individuals might end up evaluating a label that differs from its final production appearance.

Conclusion

In summary, reliance on manual or fragmented content management systems exposes organizations to avoidable risks, inefficiencies, and compliance gaps throughout the clinical trial labeling process. Streamlining workflows by integrating an automated, centralized phrase library not only enhances accuracy and consistency but also safeguards auditability and regulatory compliance. By embracing modern, unified solutions, organizations can ensure that clinical trial labels meet the highest standards of clarity and reliability, ultimately supporting patient safety and successful trial outcomes.

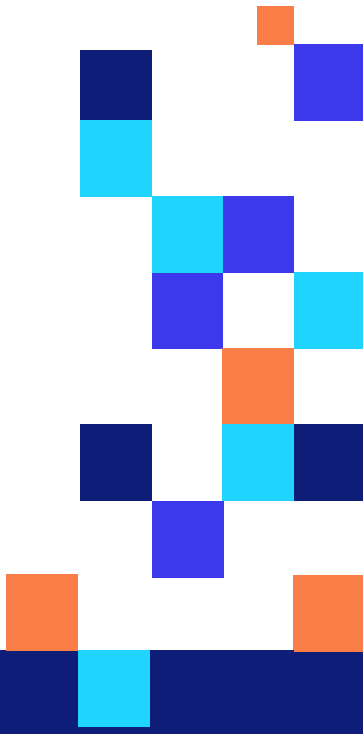
Click here to watch our webinar “Mastering the translation of clinical trial labels.”

About Loftware Cloud Clinical Trials

Loftware Cloud Clinical Trials (previously Loftware Prisym 360) streamlines clinical supplies labeling and content management – it’s built into our software’s DNA. Our solution simplifies complexities and shortens timelines to deliver GxP-compliant labeling with consistency, accuracy, and speed.

At Loftware, we know a label is not just text and images, it’s a complex structure of content and data that lays beneath. From variable text to country specific requirements and regulatory compliance, every detail matters.

But we pride ourselves on knowing these intricacies. That’s our business. To provide you with a validation ready cloud-based labeling solution that’s simple, agile, and scalable. We enable you to get trials to market quicker and more cost effectively, while allowing you to do what you do best… delivering patients a safe, positive, and effective trial outcome.



Loftware is the global leader in cloud-based labeling and artwork management solutions, helping businesses improve accuracy, traceability, and compliance while enhancing speed and efficiency. With a presence across six countries and a network of over 500 industry experts and 1,000 partners, Loftware enables companies to meet evolving customer and regulatory requirements. Our solutions support global supply chains, printing over 51 billion labels annually and saving businesses over $200 million in fines each year. Trusted by industries from pharmaceuticals to automotive, Loftware empowers organizations to drive digital transformation and ensure brand integrity. Learn more at **Loftware.com**

US • GERMANY • UK • SLOVENIA • SINGAPORE