

REASONS FOR BUILDING AN APPROVED PHRASE LIBRARY

patheon

- API
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Introduction

The challenge of creating labels for investigational drugs is mounting as more countries sign on to participate in clinical trials. Delays in translating and approving clinical labels—a process that averages about 120 business days—can prevent clinical trials from starting on time and threaten to derail development timelines.

The issue boils down to one of process and priorities. Affiliates responsible for translating and approving labels often postpone the time-consuming process to address other pressing matters, causing delays. Since translations are performed manually, inconsistencies and errors frequently result, the potential consequences of which can be more serious than merely having to correct or reprint the label.

A proven solution to the problem of label creation is the use of an approved phrase library, an electronic repository of globally consistent, multi-language terminology that virtually eliminates the need for manual translation. With a single mouse click, the library automatically translates label text into multiple languages. Implementation

of an approved phrase library has been shown to shorten label cycle times by more than 50%, improving clarity and consistency and reducing the workloads of clinical teams and affiliate staff.

As a global leader in clinical supply chain management, our Clinical Label Services team is setting the pace for improved translation management with the use of ATLASSM (Alternative Translation and Label Approval System). ATLAS—the only system available to address the full spectrum of label development, from text translation and approval through label manufacturing. This ebook discusses the challenges of translating and approving label text, and how an approved phrase library can reduce label timelines, improve quality, and assure regulatory compliance.



Label issues are cited by regulators as a major reason for rejecting New Drug Applications (NDA)



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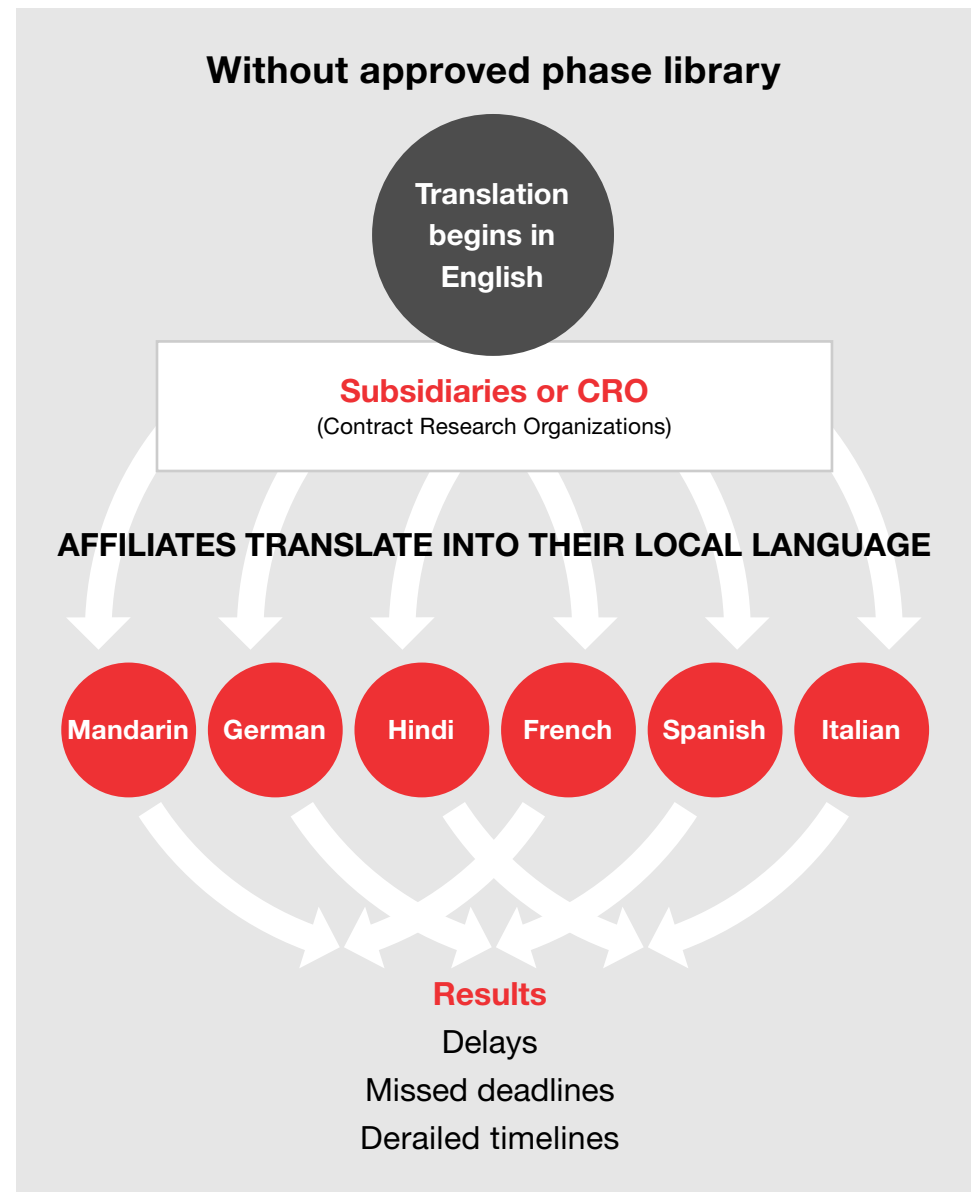
Risks of not building a phrase library

The average timeline of 120 business days to generate approved text for a clinical label involves the collective effort of hundreds of individuals across the globe.

The responsibility for translating and approving labels falls on company affiliates, usually subsidiaries or Contract Research Organizations (CRO). The process begins with the drafting of label text in English by a project manager, who routes the template to affiliates.

Affiliates must manually translate the text into their local languages, review it to ensure that it meets local regulatory requirements, and approve it—all before the study can commence. For some large multi-national trials, label text may require translation into dozens of languages. In addition to the time commitment of translating a label, there are often as many as 10 individuals in a single country who must approve it.

Affiliates have heavy workloads. They often relegate label translation to a back burner while they address a host of other priorities, such as manufacturing, distribution and especially patient recruitment. The result: delays, missed deadlines and the possibility that a trial might not begin on time, potentially derailing the development timeline.



Benefits of building an approved phrase library

The use of an approved phrase library simplifies the process of label translation and approval—improving clarity and consistency, easing workloads and, importantly, reducing cycle times.

Greater clarity and consistency

There are as many ways to translate the same phrase as there are translators, each of whom has a personal preference. Consider, for example, the phrase “Take one capsule one time per day,” which can also be expressed as “Take one capsule daily,” “Take one capsule once a day,” and even “Take one capsule at any time during the day.” While all are technically correct, the inclusion of different translations of the same instructions in the label is inconsistent.

Clear, consistent language ensures that all patients in a clinical trial receive identical instructions. Repeat use of the same phrase provides the clarity and consistency that are valued by regulatory agencies.

In creating an approved phrase library, standard translations are developed for each commonly used phrase in every language. These approved phrases then automatically populate whenever a label is created and routed to affiliates for translation and approval. Clients have the option of building their own custom repository of standard phrases or accessing the body of standard phrases provided in ATLAS.

Standardization and predictability

By building a library of approved phrases, each affiliate approver is assured of signing off on identical language.



Clarity and consistency are valued by regulatory agencies

Less interpretation

In some affiliates, individuals responsible for translating label text may create and share a list or spreadsheet of translations for commonly used phrases. The translations may be stored on a desktop or shared drive. Over time, new phrases are added and others revised, reflecting individual interpretations and preferences, and potentially resulting in many different versions of the same phrases. The use of an approved phrase library eliminates the need for local lists/spreadsheets, as well as subjective interpretation.

Decreased risk of errors

When translations are performed manually, human error can occur. It is during the process of retyping and editing that variations are likely to creep into text, and a misspelled, transposed or dropped word can drastically alter the meaning of a word or phrase in some languages.

Project managers cannot be expected to understand every language and may not recognize translation errors. As a result, labels containing errors could be printed and distributed, a problem that can cost thousands of dollars to correct. The use of an approved phrase library ensures the accuracy of phrases and minimizes the need for translating, retyping or editing.

Eliminate errors, individual interpretations and preferences

瓶 – bottle
小瓶 – vial



- ✓ Förvaras utom räckhåll för barn.
Keep out of reach of children
- ✗ Förvaras räckhåll för barn.
Keep in reach of children

- ✓ 仅限临床试验使用
For clinical trial use only
- ✗ 仅限床试验使用
Limit to bed experiment use

Benefits of building an approved phrase library



Flexible revisions

Should the study protocol be revised, as is frequently the case, an approved phrase library provides the flexibility of revising only those portions of the label that require change. The entire label does not have to be translated and approved again.



Reduced workloads

Translating label text is often considered to be the least critical part of affiliates' jobs. Experience shows that an approved phrase library can halve the time it takes affiliates to translate, review and approve. This turns a labor-intensive, time-consuming task into speedy review and approval. By reducing translation and approval time, affiliates can concentrate on other pressing matters.



Curtailed costs

Translating a label often requires the services of a translation company, a cost that is passed on, especially when using CROs. Once a standard phrase library is established and in use the need to hire translation companies diminishes sharply.



Shorter cycle times

An approved phrase library means that much of the work of translating is already done when a label reaches affiliates, shortening the cycle time significantly. Instead of translating 20 phrases, affiliates may have to translate only one or two new phrases. These new phrases can then be standardized and added to the library for future use.

REDUCE TIME & COST



Approved phrase library can reduce the time and save cost to translate, review and approve label.

Case study: Speeding label approval

ATLASSM

ATLAS and its approved phrase library is making it possible to significantly reduce the label translation and approval timeline—in some cases by more than half—as it has for two pharmaceutical clients. While it took time to establish a customized global process for these clients, they are reaping the benefits of the process while being able to use the metrics for continuous process improvement.

A large pharmaceutical client was averaging 127 days to finalize label text. The company implemented full ATLAS service, including online ordering, regulatory content, management of approvals and, of course, an approved phrase library. It took about three months to finalize the process, build the custom library, develop documentation and provide training in advance of the date the system went live.

The effort was well invested: In the initial experience, finalizing label text took 57 days, an immediate savings of 60 days, from the start date.



ATLASSM

The industry's first clinical, web-based, label-specific translation and approval management system, ATLAS, that comprehensively addresses the full spectrum of label development, streamlining the process from text translation and approval through label manufacturing.

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