ThermoFisher SCIENTIFIC

USING AN APPROVED PHRASE LIBRARY

patheon

- API
- BIOLOGICS
- VIRAL VECTOR SERVICES
- EARLY & LATE PHASE DEVELOPMENT
- **CLINICAL TRIAL SOLUTIONS**
- LOGISTICS SERVICES
- COMMERCIAL MANUFACTURING

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, Fisher Clinical Services is setting the pace for improved translation management with the use of ATLAS℠ (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)

Our Clinical Label Services team is setting the pace for improved label translation management with the use of ATLAS℠

Beginning the label process

START

Establish the order in the online system

1

Entering the label attributes including:

- size of the study
- study number
- other specific details

2

Enter or load the contacts to whom the label should be sent into the system.

3

Select the required English phrases from a drop-down menu

仅限临床试验使用

For clinical trial use only

4

NOTE: It isn't necessary to manually select all of the corresponding translations. The Library automatically populates the phrases in all of the relevant languages, exporting the label copy in the appropriate languages to be sent to the right contacts.

5

In the end, instead of having to translating as many as 500 phrases, it's likely that fewer than 20 specific phrases will require translation. The process is completely paperless; affiliates can translate, review and approve electronically—including electronic signatures.

END

Storing local regulatory requirements

Local regulatory authorities may mandate inclusion of certain phrases in a label, one example of which is “for clinical trial use only”. These phrases are stored in separate areas of the repository. When a particular type of label is selected—such as a small vial, for instance—any additional country-specific phrases will automatically populate.

This feature saves affiliate time and work. It replaces the need to route all-English text and make country approvers responsible for both translating text and adding country-specific phrases. With an approved phrase library, it all comes together at once.

Local regulatory authorities may mandate inclusion of certain phrases...

Other key features

Web-based for convenience

The library is located on a secure website, requiring only internet access to gain access. Users can pull phrases from the library, review and approve label copy from anywhere in the world.

24/7 Access from anywhere

Users can log in virtually anywhere at any time—in the office, at home or while traveling—providing maximum flexibility.

Automatic reminders

Scheduled email triggers remind affiliates about deadlines for translation and approval.

Most current phrases only

The system ensures that only the current phrases are being used, versus other system

Revisions with change control

The library captures revisions and phrase updates, while blocking unapproved phrases. In addition to capturing legitimate updates, the system notes the identity and location of the individual who requested the change. This provides version control that is missing when individuals maintain spreadsheets of commonly-used phrases on their desktops.

Limited access with single administrator

The system permits the administrator to provide users with access only to the areas they need to see—e.g., if responsible for pulling phrases, access to do only that; if an approver, access only for approvals. In addition, the administrator can determine who is authorized to make changes, ensuring the integrity of the library.

Accommodating changes over time

MISCONCEPTION:

Phrases used in an approved phrase library change over time.

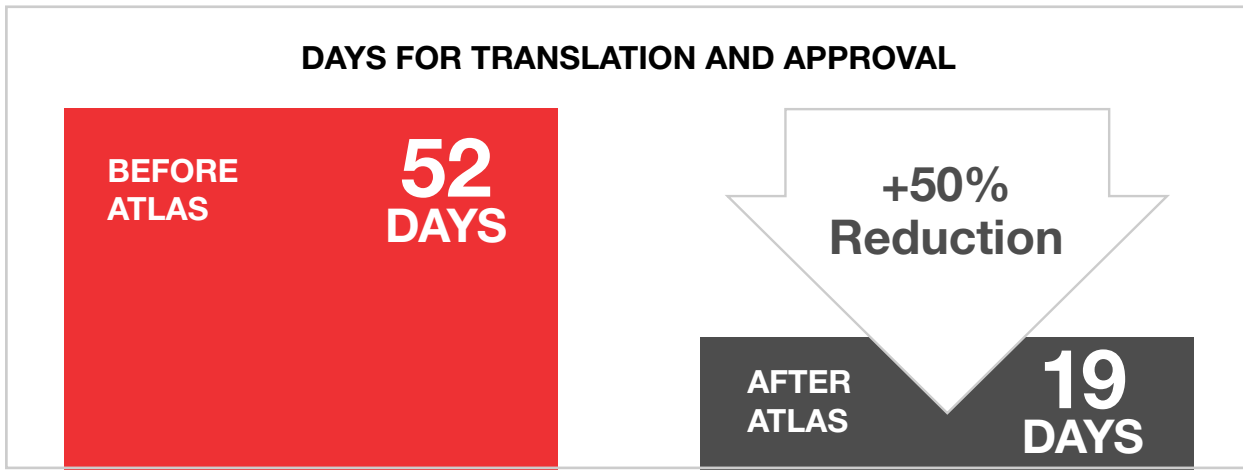
TRUTH:

Phrases do not change over time, although preferences for phrases may. While one phrase may be preferred over another, personal preference does not render a different translation of the same phrase incorrect. Clients can customize the library to reflect changing phrase preferences.

TRUTH:

Regulatory requirements, on the other hand, can and do change. In addition to storing standard phrases, the library is a repository for viewing the latest regulatory templates and requirements, which can be updated as often as necessary.

Case study: Speeding label approval



A leading pharmaceutical company selected as a pilot a large Phase III clinical trial with clinical sites in 18 countries. Its translation and approval process had been taking about 52 days:

- Supply core text—1 day
- Compile translations—5 days
- Route documents—2 days
- Affiliates approve text—20 days
- Create proofs—5 days
- Proofs final review—2 days
- Final proof review—15 days
- Final quality review—2 days

The use of an Approved Phrase Library reduced the timeline by more than 50%—from 52 days to 19 days:

- Supply core text—1 day
- Compile translations—3 days
- Create proofs—1 day
- Route proofs—1 day
- Affiliates approve proofs—8 days
- Client quality proof review—5 days

ATLAS℠

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.

+1 919 226 3200 • thermofisher.com/patheon • pharmaservices@thermofisher.com

Published 09/21

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