



TRANSPERFECT  
LIFE SCIENCES

# Multilingual Labeling:

CONSIDERATIONS  
FOR EFFICIENT,  
COST EFFECTIVE  
AND COMPLIANT  
LABELING

## Included in This Guide:

- Key solutions for navigating global labeling
- Considerations for seamless multilingual product labeling



## KEY TAKEAWAYS

Accurate and compliant labeling of an investigational medicinal product (IMP) is an important and integral part of clinical trial operations. A misstep in labeling can lead to significant delays, affecting the entire study's timeline and potentially incurring costs ranging from \$100,000 to \$700,000 in hard expenses. In worst-case scenarios, incorrect labeling might necessitate a complete product reproduction. Learn more about the strategies and solutions leading sponsors are leveraging to ensure excellence and efficiency in IMP labeling for clinical trials.

### **Section 1**

#### *How Leading Sponsors Augment Labeling Operations for Efficiency and Compliance*

Learn about the key solutions global sponsors are leveraging to ensure efficient labeling operations.

### **Section 2**

#### *Quick Guide: Fast, Cost-Effective, Risk Controlled Global IMP Labeling*

Discover essential steps for seamless product labeling in global markets.

Section 1

# **How Leading Sponsors Augment Labeling Operations for Efficiency and Compliance**

# STRATEGY, AUTHORIZING, AND LOCALIZATION SOLUTIONS TO IMPROVE LABELING OPERATIONS

Patients and healthcare professionals around the world depend on product labels that have been effectively localized for safety and effective treatment. Accurate and culturally relevant labeling ensures comprehension of usage, dosage, and safety information, which in turn facilitates wider product acceptance and adherence to local regulatory standards. With proper augmentation to their technology and resource infrastructure, global sponsors in the pharmaceutical industry can achieve near 100% compliance, 50% faster timelines, and 98.5% first-time approval.

Here are some key solutions they leverage to successfully navigate global labeling requirements, broken into three categories: Strategy, Authoring, and Localization.

## Strategy

### *Regulatory Compliance Services*

Stringent validation processes help ensure product labels comply with regulatory requirements in different countries. This includes checking for compliance with local laws regarding language, content, and layout of labels, as well as working closely with regulatory authorities to ensure that labels meet all necessary guidelines and requirements. Legal experts should then review labels to ensure compliance with international and local legal requirements and to mitigate the risk of liability.

## Authoring

### *Generative AI*

GenAI is a vital tool for enhancing efficiency and accuracy in clinical trial material management. It can potentially be useful for handling the intricacies of multi-language labeling and regulatory compliance, reducing time and errors and facilitating smoother clinical trial operations. Clinical labeling managers and regulatory affairs specialists can use genAI to automate and streamline the IMP labeling process, ensuring labels are accurate, compliant, and tailored for global clinical trials.

### *Label Management Software*

Labeling managers can use advanced software solutions to streamline the creation, approval, and revision of product labels. These systems often include features for version control, audit trails, and integration with translation management tools.

### *Structured Content Management Systems (SCMS)*

These systems can handle multilingual content as well as manage label text as components. This ensures that label translation remains consistent and error-free across multiple versions. Additionally, an SCMS enables faster processing of label updates as well as new label creation by recycling existing components.

### *Graphic Design and Layout Services*

Proper translation is crucial, but labels should also be aesthetically pleasing, functional, and compliant with regional regulations—especially when adapting to multiple languages and scripts.

### *Patient-Centric Design Approaches*

Patient feedback during the design process can provide valuable firsthand insight into patient comprehension and usability.

### *Regulatory Writing*

It's important that labels and supporting documentation are in line with regulatory requirements as well as consistent with other product information.

### *Quality Assurance and Testing*

Rigorous quality control processes, including in-country review, will ensure the accuracy and appropriateness of the translated labels.

### *eLabeling Solutions*

Electronic labeling solutions such as QR codes can provide quick access to multilingual label information.

## **Localization**

### *Professional Translation and Localization Services*

Linguistic accuracy is vital, but it's not enough. Label content must also be culturally and contextually appropriate for each target market. Professional translators and localization experts can ensure labels hit the mark.

### *Translation Memory Tools*

Storing previously translated phrases and sentences helps maintain consistency across product labels and reduces the time and cost of future translations.

Section 2

# Quick Guide:

FAST, COST-EFFECTIVE, RISK

CONTROLLED GLOBAL IMP LABELING



## ENSURING COMPLIANT, TRANSLATED, AND CERTIFIED IMP LABELS FOR ANY COUNTRY OR LANGUAGE

Global sponsors can follow these steps for an efficient, cost-effective, and compliant labeling solution that is suitable for global markets and diverse patient populations:

### Initial Strategy and Compliance Planning

- Identify the internal stakeholders involved in your label creation processes and consider whose signoff is required for label approvals (clinical, quality assurance, regulatory affairs, etc.).
- Do a gap analysis of internal resources and knowledge across the global markets in which you will be conducting clinical trials.
- Find a specialized partner with deep and wide experience across all of your target markets and therapeutic areas and previously identified gaps.
- Identify communication pathways on a study level to ensure all internal and external stakeholders have a clear way of working toward critical deadlines and avoiding study delays.

### Master English Label Creation and Design

- Identify software tools that can be used to store and monitor compliance of label phrases to more efficiently produce clinical trial labels, with a focus on structured content and content reuse.
- Implement graphic design services to ensure labels are both functional and compliant with regional standards.

## Quality Assurance and Localization

- Utilize a partner who can support everything from Master English label creation to in-country regulatory reviews, through to professional translation and localization services for local language labeling.
- Apply translation memory tools to maintain consistency across clinical labels glossaries, regulatory-required terminology, and various label versions.
- Conduct rigorous quality-control checks, including in-country reviews, and a proof-approval step prior to label printing.

## Integration and Technology Utilization

- Integrate label management with eTMF systems for seamless document management and tracking.
- Use electronic labeling solutions such as QR codes to enable easier access to multilingual label information.

## Continuous Monitoring and Improvement

- Regularly review and update labeling processes, technologies, and vendor performance to maintain quality and efficiency.





# Take the Next Step

Request more information about  
IMP labeling services at TransPerfect Life Sciences.

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