



## REGULATORY LANGUAGE SUPPORT TO REMEDY COMMON CLINICAL LABELING CHALLENGES AND IMPROVE EFFICIENCY

TRANSLATIONS FOR  
5 DIFFERENT COUNTRIES

MULTIPLE LOCATIONS

FULLY COMPLIANT,  
COUNTRY-SPECIFIC LABELS

### About the Customer

The customer is a leading Life Sciences company which provides services solutions for drug development, clinical trial logistics, and commercial manufacturing and packaging. With multiple locations around the world, they help their customers accelerate Life Sciences research, solve complex analytical challenges, improve patient diagnostics, deliver medicines to market, and increase laboratory productivity.

**As a best-in-class provider of pharma services solutions, our customer is responsible for supporting clinical trials and facilitating commercial manufacturing and packaging. Trial sponsors rely on this company to help manage the clinical trial lifecycle, a crucial part of which is clinical labeling.**

Because clinical labeling helps to ensure the safety and wellbeing of clinical trial participants, specialist knowledge, effective communication, and seamless collaboration are critical to the success of labeling projects. One of the key steps involves a technique called core text creation wherein subject matter experts work to create a Master English Label Text (MELT) based on the source material provided by the customer.

The MELT file contains important information gathered from the clinical trial essential documents such as protocol synopsis. Once finalized, it can be adapted to fit different packaging types (e.g. cartons, vials, bottles, syringes) and adhere to

unique regional regulations. Using English as a pivot language, the master text and its different versions can be translated into multiple languages and disseminated to participating regions.

On behalf of their end client, a pharmaceutical trial sponsor, the customer sought core text creation services concerning a lead drug candidate for multiple neuropsychiatric indications including:

- Schizophrenia
- Bipolar Disorder (BD)
- Major Depressive Disorder (MDD)
- Behavioral and Psychotic Symptoms of Dementia or Alzheimer's disease (BPSD)
- Parkinson's Disease Psychosis (PDP)
- Attention Deficit Hyperactivity Disorder (ADHD)



## The Challenge

Initially, the customer tasked Lionbridge with only core text creation; however, they later elected Lionbridge to carry out MELT adaptations and translations as well.

To successfully carry out this project, understanding of the customer's needs and requirements would be the principal concern, followed by adapting the core text and delivering translations for five different countries. Lionbridge helped the customer overcome the following challenges, including the need to:

- Facilitate clear communication and confirm mandatory elements for core text creation
- Uncover and resolve discrepancies within source material
- Adapt core text in accordance with regulatory requirements for each country
- Create and execute translation workflows in a timely manner

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## The Solution

Lionbridge worked closely with the Life Sciences customer to develop a deep understanding of their labeling needs and design a plan of action that would both satisfy immediate objectives and leave a lasting positive impression with the customer. Decisive factors in the success of the project included Lionbridge's ability to:

- Perform a targeted and detailed informational investigation and ascertain key information
- Engage in close collaboration with customer and end-client (trial sponsor) to remedy inconsistencies as they appeared in the source material
- Leverage subject matter experts and industry experience to design efficient and effective workflows
- Execute rigorous multi-step translation procedures including forward and backward translation, as well as comparative review
- Perform regulatory validation and review of deliverables against regulatory requirements

## The Results

Thanks to its deep knowledge and expertise of clinical labeling, Lionbridge was able to produce fully compliant, country-specific labels in English as well as accurate translations that maintained appropriate industry and medical terminology in each language. Working with Lionbridge enabled the customer to:

- Quickly troubleshoot issues and deliver on time
- Adhere to stringent clinical labeling standards
- Optimize workflow by using a singular vendor for the MELT creation, regulatory validation, and translation services

