# Clinical trial label services

# Label design, translation, and manufacturing – done correctly on time, every time

The challenge of creating labels for investigational drugs increases dramatically as more countries sign on to participate in clinical trials. Every investigational medicinal product (IMP), comparator, and shipping box requires a label, and unlike other medicinal products, every clinical label design is unique to every patient. Clinical label errors can prevent clinical trials from starting on time and threaten to derail development timelines. Thermo Fisher's in-house, full-service print and label capabilities across the globe, integrated with packaging, supply chain, and logistics, ensure your clinical material will be labeled correctly on time, every time.

Regulators cite label issues as a major reason for rejecting New Drug Applications (NDAs)

In-house print shop	High quality labels	Integrated service offering
<ul> <li>In-house printing capabilities integrated with packaging for speed and efficiency</li> <li>Label printing in 4-5 days, expedited orders by request</li> <li>Pre-qualified label options for bottles, vials, syringes, blister cards, autoinjectors, sachets, and secondary packages</li> </ul>	<ul> <li>For a range of temperature specifications:         <ul> <li>2-8°C</li> <li>Frozen</li> <li>Cryogenic</li> </ul> </li> <li>Adhering to high quality GLOBAL standards</li> <li>Different materials and adhesives based on the label application and storage temperature requirements</li> <li>Durable, fully laminated labels protect data integrity</li> </ul>	<ul> <li>Primary and secondary packaging</li> <li>Supply chain optimization</li> <li>Comparator sourcing</li> <li>Ancillary sourcing</li> <li>Returns and destruction</li> <li>Storage and distribution at various temperatures</li> </ul>

# Three key needs in clinical trial labeling and how Thermo Fisher can help:

#### **SPEED**

#### Labels

- In-house printing capabilities integrated with packaging for speed and efficiency
- Choose from pre-qualified single panel, multi-page, DigiPly booklets, or ePly virtual labels

#### **Translations**

 ATLAS translations management system reduces text translation timeline by more than 50%



#### **DATA INTEGRITY**

#### Labels

- Labels made from durable materials
- Variable patient data laminated to prevent smudging
- Relabel capabilities integrated with comparator studies

### **Translations**

 24/7 secure web-based system with admin-configurable user access, version control, and activity tracking features

# **ACCURACY**

#### Labels

 100% automated camera inspections of black text and optical character recognition (OCR) of variable text

## **Translations**

 Utilizing certified phrases from a validated system ensures accuracy

Our Basel, Switzerland packaging center of excellence is a great representation of our extensive labeling and packaging capabilities. Watch the video to learn more.



<u>Learn more</u> about our comprehensive clinical trial labeling services.

