LIONBRIDGE

Clinical Labeling on the Critical Path to First Patient In (FPI)

How mature labeling operating models enable faster, more predictable global study start-up

A practical perspective for Sponsors, CDMOs, and Clinical Supply organizations responsible for global study start-up execution.

Clinical Labeling is a Structural Determinant of First Patient In (FPI)

As study start-up timelines compress and trials globalize, execution dependencies between protocol finalization and site activation increasingly determine whether programs progress as planned, with labeling readiness directly affecting supply release and site activation.

Across Sponsors, CDMOs, and Clinical Supply organizations, labeling performance directly affects the ability to initiate studies as planned because label content is a regulated component of investigational medicinal product distribution.

For many organizations, the challenge is no longer access to labeling expertise. It is the operating model through which labeling is executed, coordinated, and governed across functions, as reflected in industry initiatives focused on harmonized clinical content structure and reuse.

This paper examines:

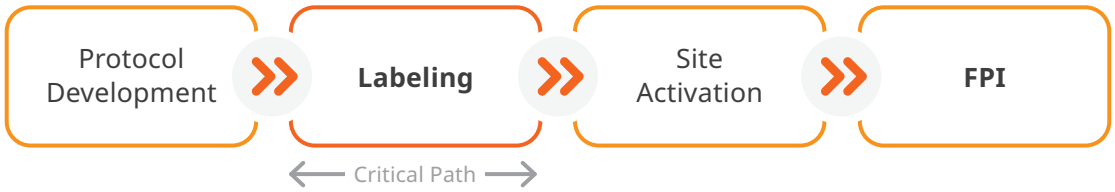
- Why labeling delays persist despite experienced teams
- Where traditional labeling models break under scale and change
- What differentiates mature labeling operating models from reactive ones

This whitepaper provides a practical evaluation of whether current labeling operating models adequately support the realities of global clinical study execution in 2026.

This perspective reflects labeling execution patterns observed across a wide range of global clinical programs spanning Sponsors, CDMOs, and Clinical Supply organizations.

Labeling on The Critical Path to First Patient In (FPI)

Labeling misalignment or delays will hinder study launch



Late labeling readiness hinders FPI

The 2026 Clinical Labeling Reality: What Has Actually Changed

In practice, Sponsors, CDMOs, and Clinical Supply organizations are now managing:

- Multiple studies progressing in parallel, often across regions with divergent regulatory expectations
- Modern complex study designs with Master Protocols or Adaptive study designs, challenging protocol execution, and demanding swift change implementation
- Increased sensitivity to label text consistency across countries, sites, and study phases
- Reduced tolerance for late-stage label changes, reprints, and packaging disruption
- Labeling dependencies embedded within clinical supply, packaging, and release workflows
- Internal teams stretched across vendor coordination, review cycles, and issue resolution

Global execution has become the norm rather than the exception. Many organizations now support studies spanning 100 or more countries and multiple languages, thus increasing the importance of consistency and controlled variation.

Instead, they appear as delayed site activation, extended-release timelines, or last-minute regulatory questions, often too late to correct without impact.

What Happens to Consistency as Trials Scale Globally?

GLOBAL REACH
Expand trial access worldwide

VS

GLOBAL CONSISTENCY
Ensure uniform trial standards

> **"Labeling issues rarely present themselves as labeling problems — They surface later as supply, release, or site activation delays."**

Mayowa Ojeyomi | Lionbridge
Global Program Director

Why Labeling Still Becomes a Bottleneck (Even in Experienced Organizations)

Capability gaps rarely drive labeling delays. They typically stem from structural friction. Across Sponsors, CDMOs, and Clinical Supply organizations, recurring failure modes include:

- **Label content treated as documents, not governed content**
  Approved language exists, but is difficult to apply consistently across studies, markets, and packaging configurations.

- **Regulatory validation and translation executed as disconnected steps**
  Each handoff introduces delay, clarification cycles, and interpretation risk, particularly across regions with nuanced regulatory expectations.

- **Change management handled manually**
  Minor updates routinely trigger effort disproportionate to the change itself, spanning revalidation, reformatting, reapproval, and supply replanning.

- **Vendor ecosystems optimized locally, rather than governed end-to-end across the labeling lifecycle**
  Translation, regulatory review, formatting, and proofing may each be high quality, but coordination between them is not structurally designed.

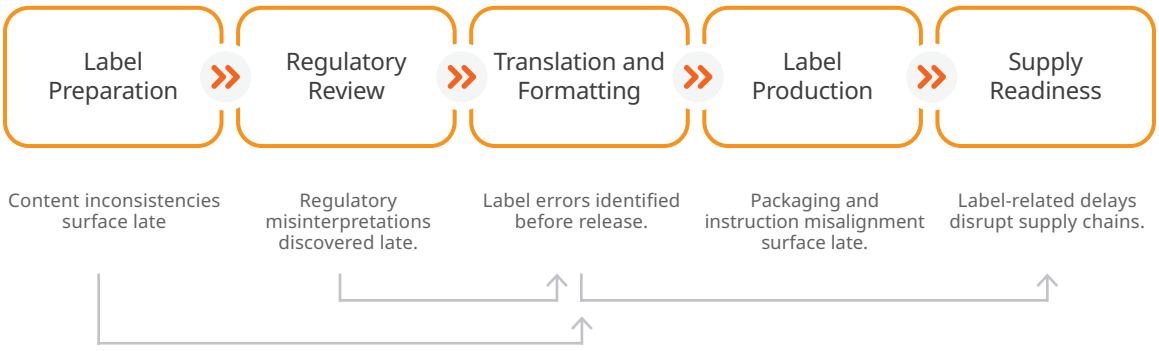
- **Inconsistent or non-reusable label language across studies and markets**
  Terminology and phrasing variations trigger additional regulatory review even when content intent has not changed.

Importantly, these delays rarely originate within individual labeling tasks. They surface at functional handoffs, often late in the process, when downstream constraints expose unresolved dependencies.

In multi-vendor operating environments, labeling maturity depends less on who executes each step and more on how compliance decision-making is governed consistently across handoffs.

Where Labeling Breaks Down in Clinical Trials

Late-stage issues often stem from process gaps, reactive handoffs, and fragmented oversight.



Issues emerge through handoffs, not tasks.

How Mature Is Your Labeling Operating Model?

In 2026, the key distinction is no longer who performs labeling tasks, but how labeling is operationalized. Mature labeling operating models share three characteristics:

1. Centralized control of label content and change logic
Approved language is governed, traceable, and applied consistently through structured regulatory and linguistic review, reducing avoidable rework.

2. Integrated regulatory and linguistic execution
Regulatory experts and linguistic specialists operate within a shared framework, reducing interpretation gaps and late revalidation.

3. Designed for scale processes
The model assumes parallel studies, multi-market execution, and ongoing change, not one-off delivery.

Organizations lacking these characteristics tend to experience labeling as a recurring constraint.

> **"As studies get more complex and global, does your labeling effort grow linearly or exponentially?"**
>
> Mayowa Ojeyomi | Lionbridge
> Global Program Director

Labeling Operating Model Maturity

How operating model design affects predictability to FPI

Scalable Operating Model
Handles parallel studies and frequent amendments effectively.

Integrated Operating Model
Aligns regulatory, linguistic, and supply considerations.

Coordinated Operating Model
Facilitates team communication and dependency management.

Reactive Operating Model
Faces challenges with late validation and high change effort.

Where Does Labeling Break Down in Your Study Start-Up?

Consider your most recent global study start-up:

- How many times was label text reworked after initial approval?
- How often did labeling readiness affect packaging, release, or site activation timing?
- How confident were teams applying previously approved label language across markets within defined review and validation processes?
- How often did linguistic changes, rather than content changes, trigger additional review or delay?

If these questions are difficult to answer consistently, the constraint is likely operating model design, not resourcing.

What Integrated Means in Practice

An integrated labeling model means:

- Master labels designed for reuse
- Validation applied early and consistently
- Translation aligned to regulatory intent
- Formatting and certification planned through defined workflows

This reduces rework and improves accountability across the labeling lifecycle. Integration does not imply single-vendor ownership of execution. It refers to how regulatory, linguistic, and supply dependencies are governed and aligned across stakeholders.

Fragmented vs. Integrated Labeling Operating Models

Fragmented Labeling Model
Disconnected handoffs
and late issue discovery

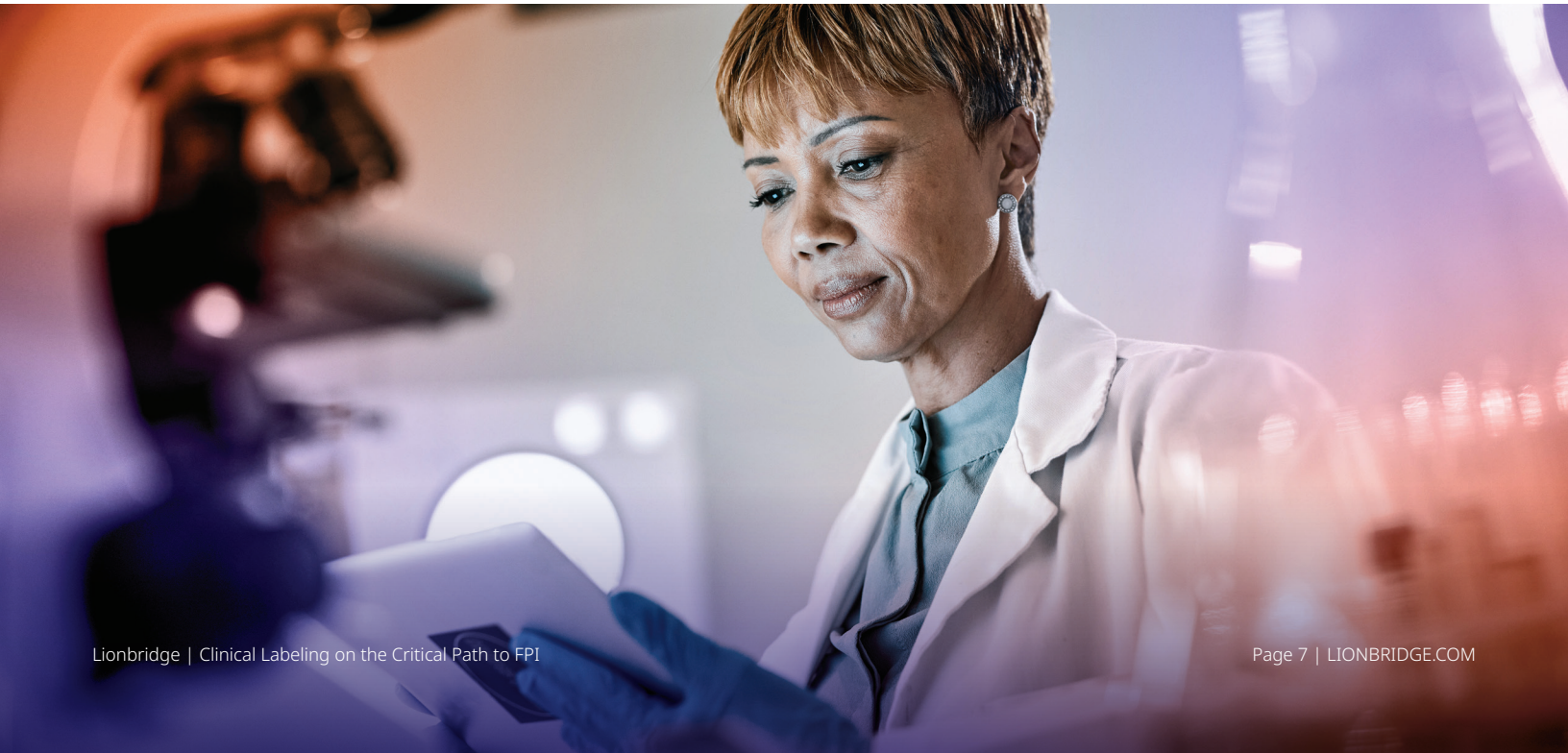
Integrated Labeling Model
Governed content and
aligned execution

Both models involve the same core activities. The difference lies in how dependencies are governed and when issues are surfaced.

Why This Matters for Sponsors, CDMOs, and Clinical Supply Organizations

For Sponsors, labeling affects study start-up timelines and regulatory confidence. For CDMOs, it influences scalability and sponsor trust. For Clinical Supply organizations, it determines packaging, release, and site activation reliability.

Across all three areas, labeling performance is a visible operational dependency, particularly in multi-vendor environments where independent regulatory oversight is critical to maintaining consistency and inspection readiness.



Regulatory Confidence is an Outcome of Design, Not Review Effort

Speed without regulatory confidence creates risk. Confidence without speed creates delay. Well-designed models resolve regulatory questions early through structured review, before locking in supply, timelines, and cost.

> **"Organizations that invest in operating model maturity reduce friction and better support global execution at scale."**

Global Scale Without Fragmentation

Global reach is common. Consistency is not. Effective operating models enable controlled variation through repeatable review processes, without unnecessary repetition across markets.

Moving Forward: A Practical Reflection

Clinical labeling need not remain a recurring source of delay or uncertainty. The question for 2026 is no longer who can label — It's which operating model supports the way you actually run trials today.

LEARN MORE AT LIONBRIDGE.COM

ABOUT LIONBRIDGE

Lionbridge partners with brands to break barriers and build bridges all over the world. For over 25 years, we have helped companies connect with their global customers and employees by delivering translation and localization solutions in 350+ languages. Through our world-class platform, we orchestrate a network of passionate experts across the globe who partner with brands to create culturally rich experiences. Relentless in our love of linguistics, we use the best of human and machine intelligence to forge understanding that resonates with our customers' clients. Based in Waltham, Massachusetts, Lionbridge maintains solution centers in 24 countries.

LEARN MORE AT
LIONBRIDGE.COM

LIONBRIDGE