NAVITAS LIFE SCIENCES

A TAKE Solutions Enterprise

Regulatory

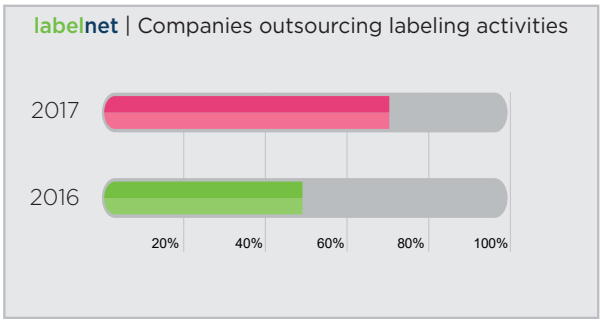
# The Case for Labeling Outsourcing

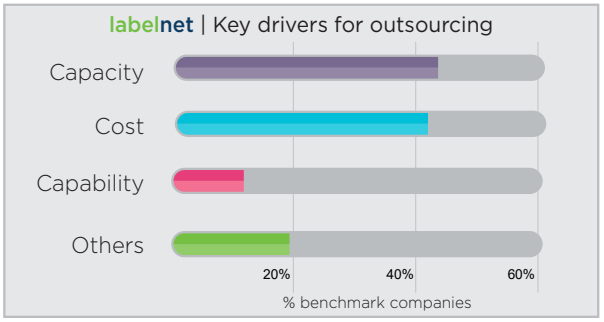
*Is labeling the next area ripe for outsourcing?*

## Why outsource?

Over the past decade, the nature of processes that pharmaceutical and biotech companies outsource has changed significantly. Many Life Sciences companies, regardless of size, have shifted from a largely in-house model to one that relies upon external partners to provide most of the transactional processes and some value-added activities as well. Vendor maturity and increasing domain experience, scalable and flexible engagement model, and the opportunity to reduce cost of operations along with improving quality and compliance in Clinical, Pharmacovigilance and other areas encouraged Life Sciences leaders to consider additional areas for outsourcing, including Regulatory Affairs.

As internal labeling processes become more mature and operations become more efficient, companies have attained higher confidence to outsource many of the Regulatory Affairs processes including labeling activities. In 2017, 70% of the 30+ labelnet* member companies were outsourcing at least 1 element of the labeling process, up from 50% in the previous year. Releasing internal capacity to focus on high value strategic activities, is cited at the number one reason for outsourcing in labeling. This article explores where there are outsourcing opportunities in the labeling process and key considerations to help ensure that favorable outcomes are achieved.




## Early evidence of labeling outsourcing reveals a piecemeal approach

Labeling is an important mechanism for communicating safety and benefit-risk information to patients and healthcare professionals. Labeling errors could pose a significant risk to patient safety, resulting in an instance of regulatory non-compliance. This in turn leads to high costs to the company, including those related to product recall and potential fines, ultimately, damaging the brand reputation.

End-to-end labeling is a critical process as it encompasses multiple stakeholder groups, from Pharmacovigilance and Regulatory to Artwork and Manufacturing; and spans from signal to patient across markets and geographies. The entire process could take years, and a single labeling change could affect multiple SKUs in several markets, with each potentially having differing requirements and approval timelines.

In comparison with other functions such as Clinical, Pharmacovigilance, and some other Regulatory Affairs processes, labeling has been kept mainly in-house. Why is this the case? Is it largely due to the risks of getting it wrong, or the complexity of the process? Is it because service providers have not quite caught on to the opportunity? Whatever the reason, one thing is clear: there is an opportunity to increase labeling outsourcing, and potential benefits are achievable in the areas of cost, capacity, capability, quality and compliance.

## Where are the opportunities to outsource labeling operations?

**Labeling processes that are defined and scalable.** Activities that require more repetitive actions can be governed by SOPs and, once established, can be partly or fully automated with minimal human intervention. These processes, such as labeling submissions, translations, tracking and data entry, QC and gap analysis, require less specialist resources and can be readily outsourced and managed at arms-length within a well-defined process and governance framework.

**Where specialist resources are required.** It can make sense, from both an operational and compliance perspective, to outsource activities such as local translations and submissions to "specialist vendors" who have the experience and SME knowledge in the local regions. These vendors could also serve as a resource to keep companies updated on changing local regulations.

**When flexible resourcing is beneficial.** Relying on an external vendor can improve capacity management by providing flexibility to accommodate fluctuations in workload and internal staffing capabilities. This is a potential competitive advantage that enables the deployment of high-value internal resources towards activities of greater strategic significance such as labeling strategy and development labeling. For this style of engagement to work well, pharma companies must ensure joint governance forums on a regular basis to ensure the vendor's capacity planning is aligned tightly with the company's forecasting model.

*labelnet is a networking forum for Labeling Professionals that is focused on the full lifecycle of labeling. For more information visit www.navitaslifesciences.com/labelnet

## Why might Companies not want to outsource labeling?

**Decreased oversight.** Given the risks associated with errors in labeling and the potential cost of remedial measures, the potential for decreased oversight is a major reason why companies may hesitate to outsource. For this reason, it is essential that pharma companies select outsourcing vendors with deep labeling expertise and insights, and proven track records, and proactively leverage technology to achieve the best possible oversight. This risk is also mitigated by having a true partnership, rather than a transactional model of engagement, with clear governance, oversight metrics and KPIs and continuous improvement processes in place.

**Poor vendor capability profile.** The labeling outsourcing vendor landscape is relatively immature, and the range of capabilities available among vendors varies widely. Lack of maturity in the following areas is likely to discourage outsourcing: labeling subject matter expertise, local and regional understanding of labeling regulatory requirements and timelines, flexibility, range of offerings, organizational stability, agility, proactivity and quality.

**Strategic reasons.** Lack of clarity on what are core* (retained) and non-core (transactional) activities, a clear business plan and roadmap for successful implementation, dearth of internal leaders with experience in outsourcing labeling activities and managing outsourced vendors, and unavailability of detailed historical data on operational metrics are some of the reasons mentioned by companies that refrain from outsourcing labeling.

## There are a number of options: finding the 'best-fit' model is key

Outsourcing your labeling activities to a reliable vendor can provide substantial benefits in the areas of capacity management, cost (mainly through economies of scale), improved oversight, quality and compliance. These benefits are achievable only if the right, 'best-fit' model is used. For successful outsourcing, an organization has to develop a well thought-out sourcing strategy, clearly map core and non-core activities, identify an internal team to identify and then manage vendors (who have the required capabilities, global coverage in regions of interest, and proven experience with similar clients), and evaluate risks and setup mitigation plans before initiating the actual implementation. Regardless of which model is chosen, clearly defined processes, a robust governance plan with roles and responsibilities, distinct escalation pathways, and pre-determined milestones will improve the likelihood of a successful implementation.

## How to de-risk the transition

Successful transition is critical to the success of your labeling outsourcing initiative. Allocation and engagement of internal resources early in the process is crucial. As some employees shift capability from 'doing' to 'managing', preparation before implementation is the key to ensure seamless transition. Identification of risks through joint discussions with the vendor of choice, along with appropriate mitigation planning, is also critical for successful transition. Clearly laid out milestones, deliverables, accountabilities and stage-gates for signoff by client go a long way in de-risking the transition. Early investment in a thorough and interactive training program with a complete quality management system will equip your employees with confidence to embrace change.

## What to do next

Are you taking advantage of the opportunities to improve the productivity and efficiency of your labeling operations through outsourcing? Labeling outsourcing is currently under-utilized among companies like yours, and offers you significant potential benefits. To realize these outcomes, your organization must select the right processes to outsource, best-fit outsourcing models and partners, as well as develop a suitable transition plan to ensure success. Getting these steps right is critical and can be challenging without prior experience in this area. An experienced advisor / implementation partner can help you navigate this process to deliver best outcomes for you and your organization.

## How can Navitas Life Sciences help?

With over 15 years' experience in domain-specific life sciences consulting, Navitas Life Sciences can help you navigate through the outsourcing process to achieve a successful outcome. We have a wealth of experience in the labeling environment, gained through numerous process consulting, system implementation, and change management projects in regulated environments conducted for a range of Life Sciences organisations, as well as unique insights gained from our industry leading regulatory networks; **labelnet**, **labelconnect**, **labeltech**, and **rimnet**.

*Core activities could include labeling strategy, regulatory authority interaction and relationship and knowledge of products that provide significant revenue.

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### About Navitas Life Sciences

Navitas Life Sciences delivers platform-driven full-service Clinical, Regulatory and Safety solutions and services. As the dedicated life sciences brand of TAKE Solutions, Navitas Life Sciences operates across North America, Europe, Asia pacific and Latin America. Navitas Life Sciences combines the knowledge and experience of three legacy brands - Ecron Acunova, Navitas, and Intelent. Thus, Navitas brings together the capabilities of a full-service CRO, a technology-led life sciences services provider, and expertise in analytics and data sciences to address critical challenges and drive outcomes for life sciences. Navitas has over 30 years of rich experience across 330+ phase I-IV clinical trials, 20+ therapeutic areas, and 40+ successful GCP/non-GCP audits. Our trial expertise is augmented by OneClinical, a platform that delivers trial oversight, analytics, and insights to drive successful study outcomes.


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