



# Clinical Supply Chain Survey Report

## SCORR Marketing and Applied Clinical Trials

**SCORR** + **APPLIED CLINICAL TRIALS**  
MARKETING



## Overview

The clinical supply chain includes several challenges that, if unmet, can result in delayed or failed clinical trials. Not only are efficient supply chain logistics required to provide sufficient drug product for patients, but often cold chain logistics are necessary to maintain the integrity of temperature-sensitive materials. Each of these must be achieved in the context of mounting concern over clinical trial costs and patient safety.

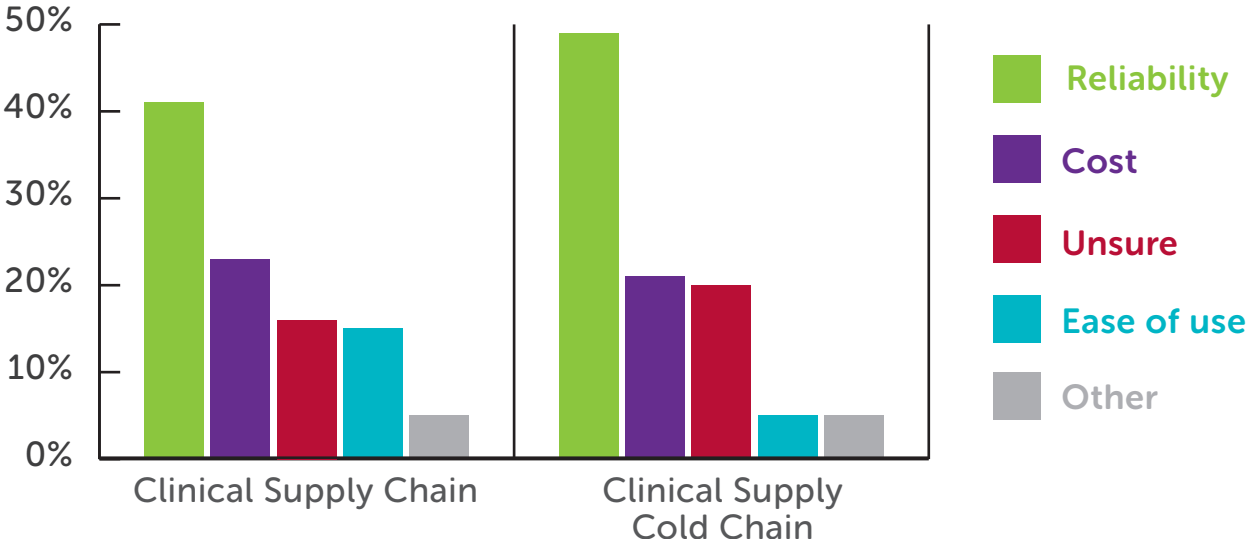
SCORR Marketing, in partnership with Applied Clinical Trials, recently conducted a survey to better understand the challenges the industry faces when attempting to get drug product and biomarker samples to the right place, at the right time and in the right way and all in a cost-efficient manner.

The survey respondents are from pharmaceutical companies, research sites, contract research organizations (CROs), academic institutions, biotech companies, service providers, consultancies, site management organizations (SMOs) and medical device companies. Their departments or job titles include research and development (R&D), clinical research associate (CRA), project management, clinical director, regulatory, corporate management, data management, strategy/planning, business development/sales, quality assurance/quality control (QA/QC) and medical affairs. Though a majority of the respondents work for companies with headquarters in North America, there were respondents from companies from five other continents: Europe, Asia, South America, Africa and Australia.

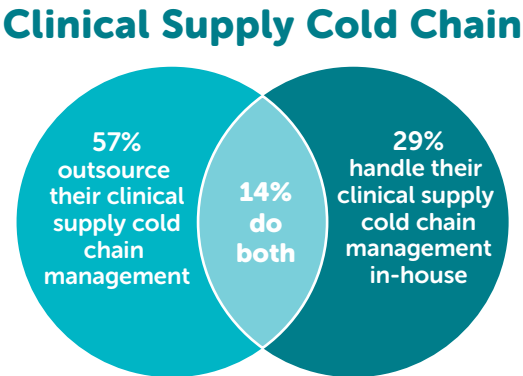
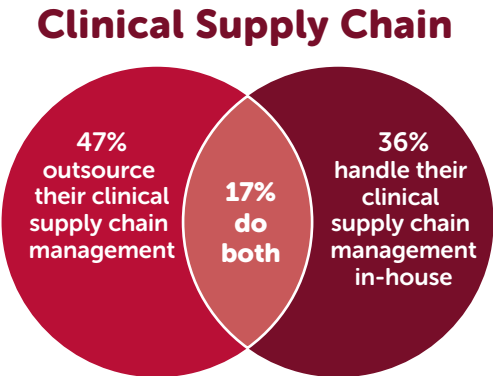
**In this survey, we gathered information on:**

- Inventory-related issues
- Prevalence and utilization of technological solutions
- Challenges at different points in the process
- Drivers of logistics decisions
- Drug product tracking
- Predictions on future trends in clinical supply chain management

# When planning supply chain logistics, what most influences your company's decisions?

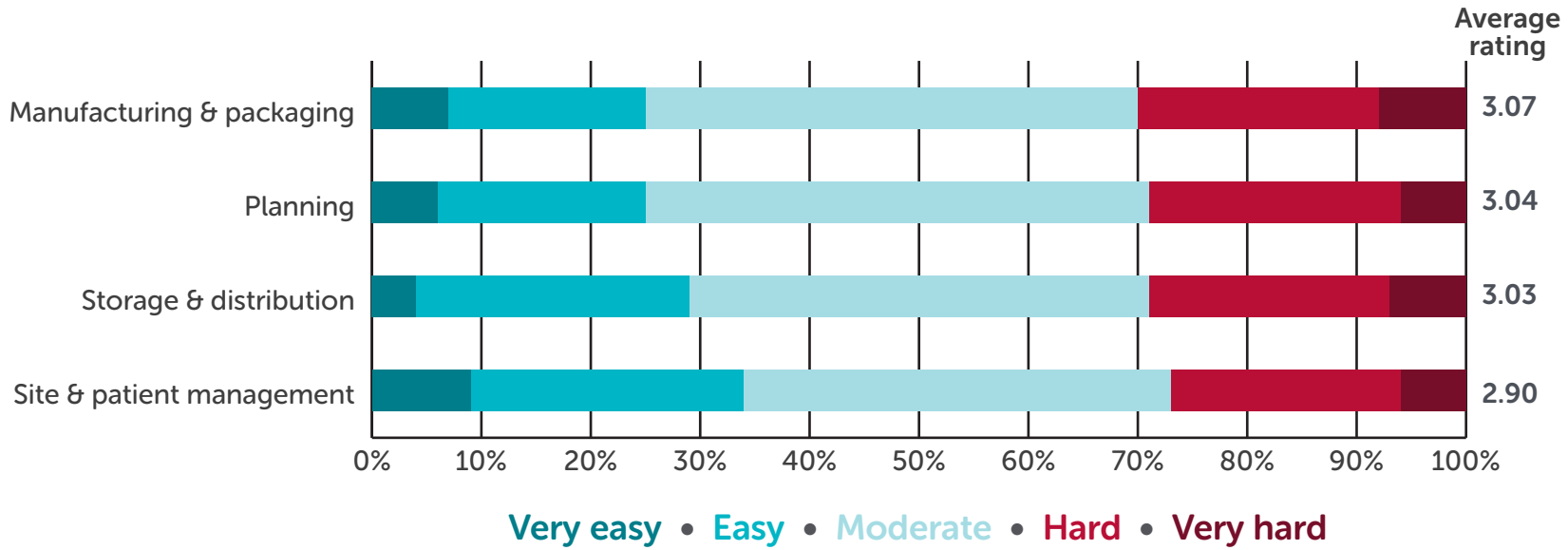


# How involved is your company in supply chain management?



# How difficult is it to manage these aspects of the supply chain process?

Responses based on a 5-point scale, with 1 representing very easy and 5 representing very hard



# How much do you outsource?

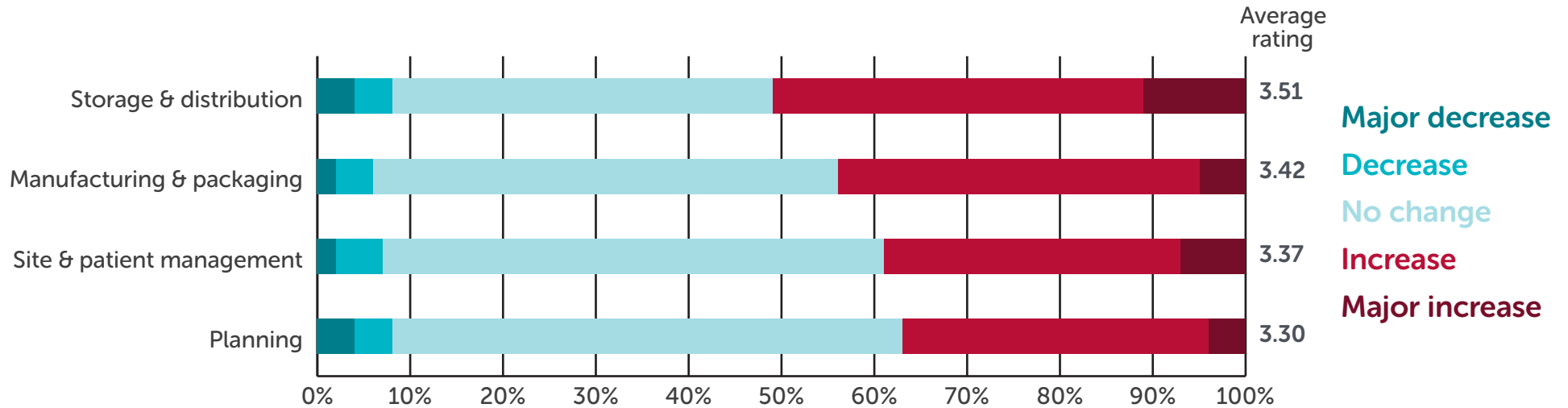
Highest rankings were indicated in the 0% and 100% areas.

	0% Outsourced	100% Outsourced
Site & patient management	39%	14%
Storage & distribution	27%	19%

	0% Outsourced	100% Outsourced
Manufacturing & packaging	26%	26%
Planning	46%	4%

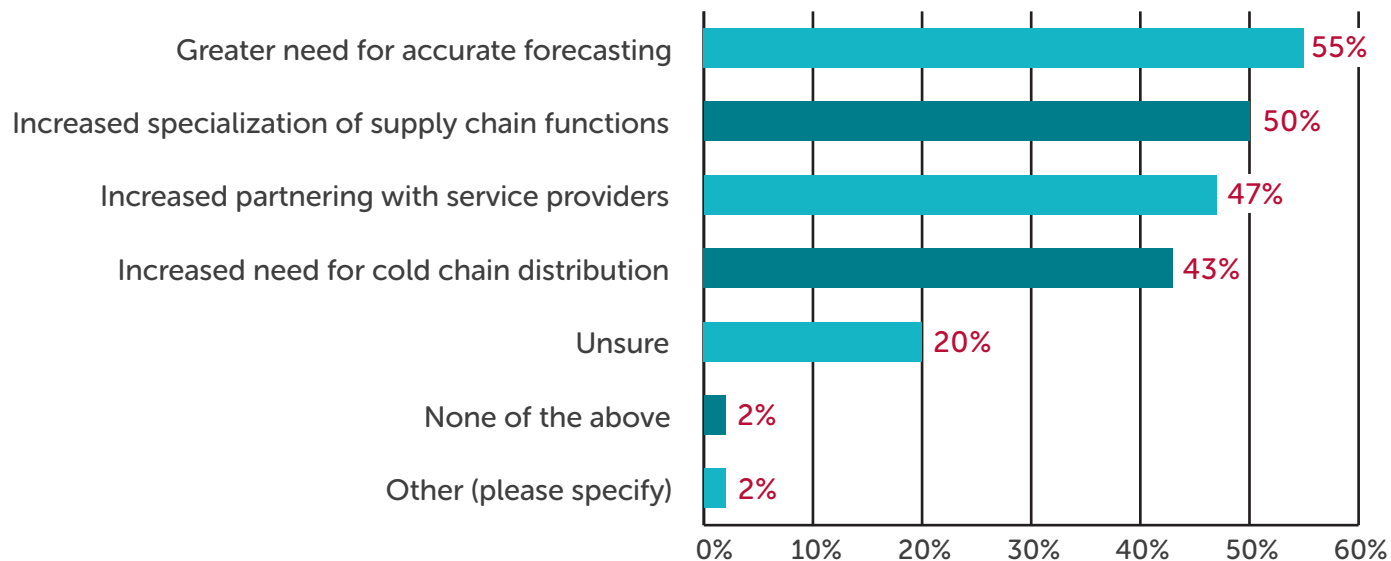
## In two years, how much will your company change its supply chain management?

Responses based on a 5-point scale, with 1 representing major decrease and 5 representing major increase

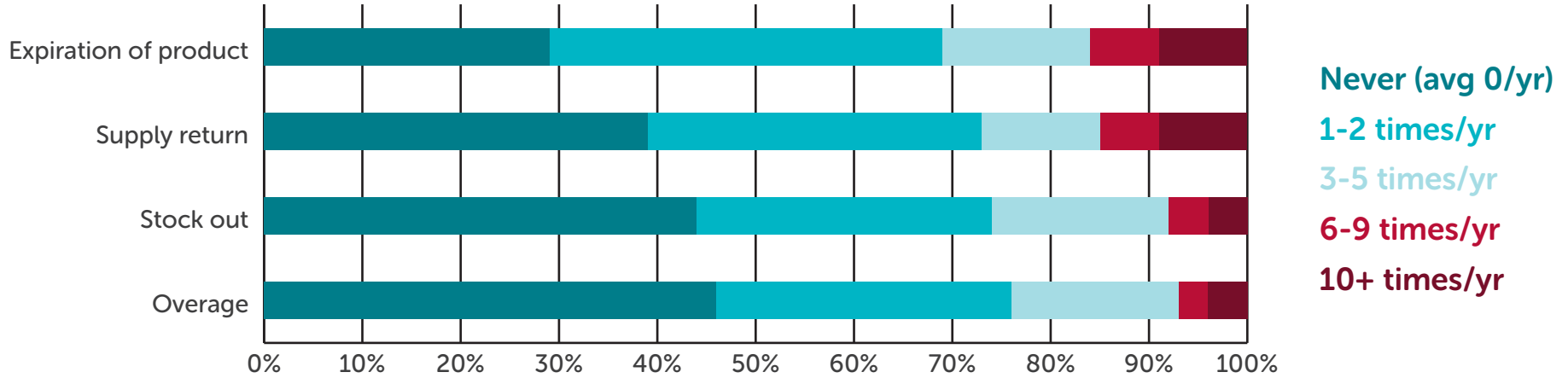


## In two years, what trends will seriously impact your company's supply chain management?

(Select all that apply.)

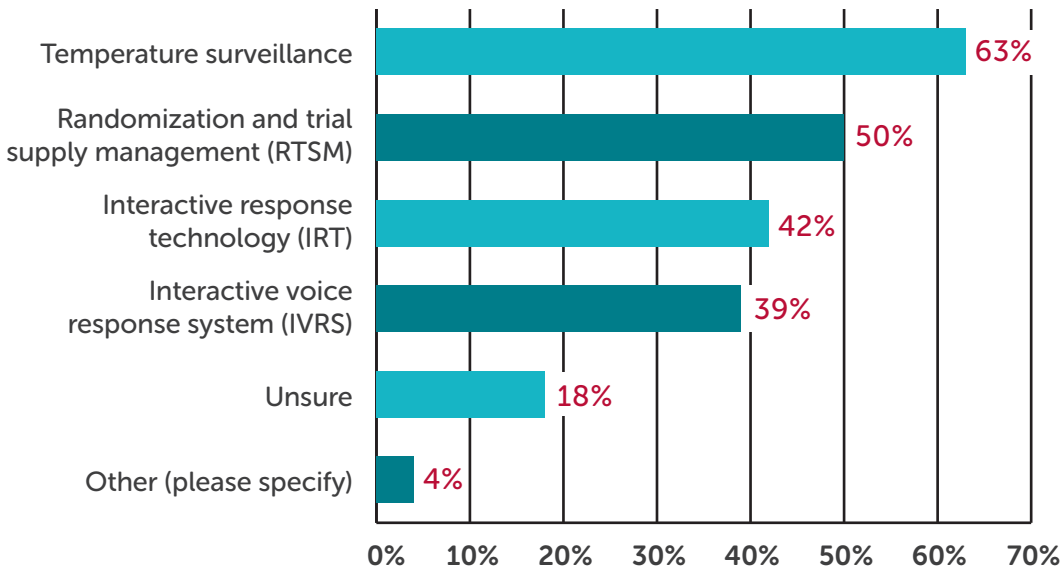


## How often does your company experience these inventory issues?

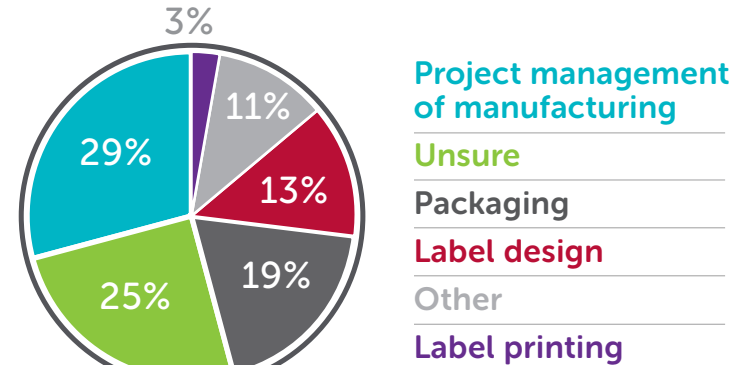


## Which of these technological solutions does your company use?

(Select all that apply.)

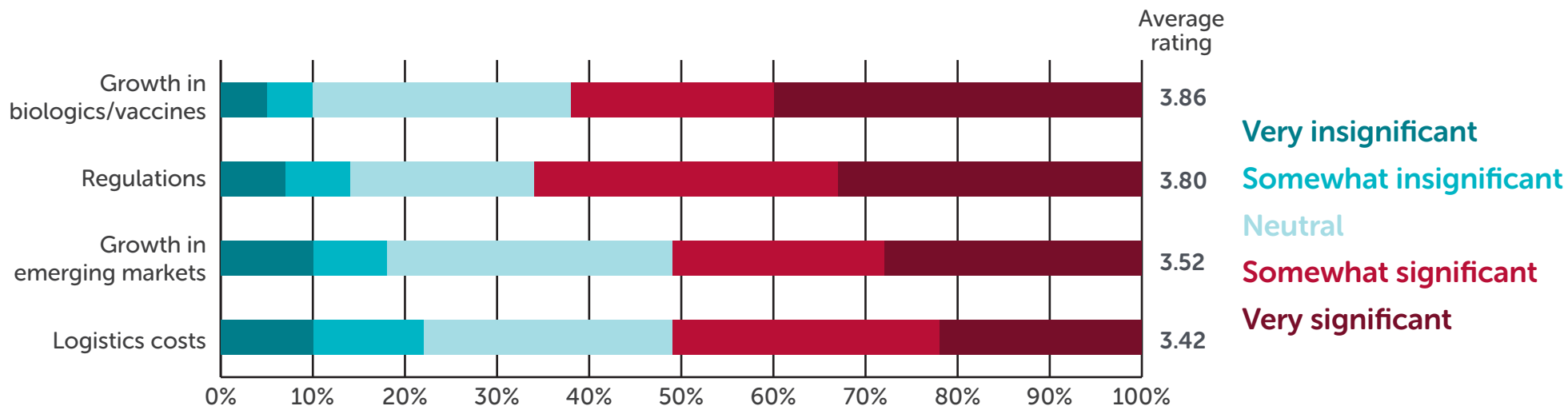


## Which aspect of manufacturing and packaging is the most challenging?



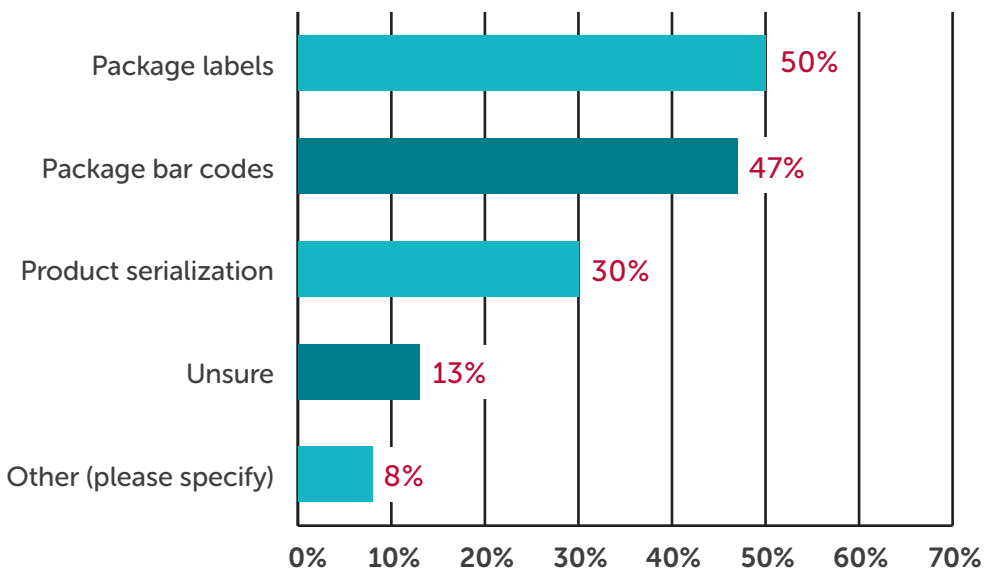
## What impact do these trends have on cold chain distribution?

Responses based on a 5 point scale, with 1 representing very insignificant and 5 representing very significant

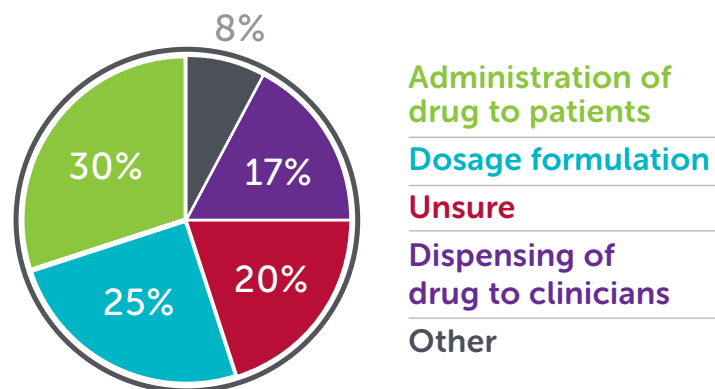


## How does your company track drug product?

(Select all that apply.)



## Which aspect of site and patient management is the most challenging?



## Three Main Points:

### 1.) When planning the logistics of supply chain management, respondents value reliability above all else.

Almost half of respondents (49%) chose reliability as the primary driver for cold chain logistics decisions. This was more than double the percentage of respondents who chose cost (21%) and almost 10 times as much as those respondents who chose ease of use (5%). Respondents from most types of organizations selected reliability as the primary driver; the exception was pharmaceutical companies, where half of the respondents (50%) identified cost as the most important reason affecting cold chain logistics decisions. Reliability was identified as the main determining factor across all job functions and company headquarter locations.

For other clinical supply chain (not cold chain) decisions, a plurality (41%) chose reliability as the No. 1 driver influencing logistical planning. There was more support here for cost (23%) and ease of use (15%) than there was when considering cold chain logistical planning. While respondents from most types of organizations identified reliability as the primary reason, there were exceptions. Once again, pharmaceutical company respondents placed the most emphasis on cost (36%) while those from academic institutions especially valued ease of use (40%). Reliability was selected as the main determinant across all job functions.

While reliability was identified as the biggest influence across continents, ease of use was selected by a higher proportion of companies not based in North America or Europe (rest of world, or ROW). For non-cold chain logistical planning, the percentage of ROW companies that identified ease of use (27%) was three times that of European companies (9%) and twice that of North American companies (13%).

### 2.) Companies that require management of their clinical supply chain are more likely to outsource management of it than to manage it themselves.

Regarding cold chain management, more than seven in 10 company respondents (71%) state their companies either outsource exclusively (57%) or do a mix of both outsourcing and managing in-house (14%). For non-cold chain management, about two-thirds of respondent organizations (64%) either just outsource (47%) or both outsource and in-house manage (17%). Companies with North American headquarters are among the exceptions; these companies are slightly more likely to at least partially manage their non-cold chain in-house (59%) than outsourced (57%).

Among the functions most likely to be outsourced are manufacturing and packaging. Slightly more than one-fourth (26%) of respondents outsource all of their manufacturing and packaging functions. Planning is on the other end of the spectrum; just 4% of respondents say they outsource all planning functions, including inventory management and forecasting. About one-half (46%) keep all aspects of planning in-house.

Research sites are more likely to keep clinical supply chain management functions in-house than are CROs. A majority of research site respondents indicate their company manages in-house all planning functions (53% of research site respondents), storage or distribution functions (60%), and site and patient management functions (also 60%). Meanwhile, smaller proportions of the CRO respondents stated their companies keep in-house all planning (8% of CRO respondents), manufacturing and packaging (0%), storage and distribution (also 0%) and site and patient management (17%) functions.



## Three Main Points (cont):

A majority of respondents (55%) believe that a greater need for accurate forecasting will seriously impact how their companies manage the clinical supply chain over the next two years. As forecasting is one of the key components of planning, this finding may seem in conflict with the previously stated sentiment that planning functions are less likely to be outsourced. However, this may indicate that respondents believe their companies will need to gain internal expertise so that they can provide more accurate forecasting in-house.

### 3.) Pharmaceutical companies and biotech companies differ on what they value most, how often they outsource, and along a variety of other issues.

As stated above regarding pharmaceutical companies, cost was identified as the biggest influence on logistical planning for both cold chain (50% of pharmaceutical company respondents) and non-cold chain (36%). Meanwhile, biotechs selected reliability as the primary driver for both cold chain (100% of biotech respondents) and non-cold chain (80%).

Biotech companies are much more inclined to outsource certain functions than are pharmaceutical companies. Three in five (60%) biotech company respondents stated that all manufacturing and packaging as well as storage and distribution functions were outsourced. For pharmaceutical companies, the corresponding figure for these functions was less than one in 10 (7%).

Biotech companies are also much more likely to utilize technological solutions such as randomization and trial supply management (RTSM). Most (89%) biotechs use RTSM, but just one-quarter (25%) of pharmaceutical companies do. The biotech percentage was by far the highest for any defined group (whether it be a type of organization, a job title or department or a company headquarter location); the pharmaceutical company percentage was the lowest for any defined group.

Additionally, biotech companies are much more concerned with certain aspects of site and patient management than are pharmaceutical companies. Three in five biotech respondents (60%) identify administration of drugs to patients as the most challenging aspect of site and patient management (compared to just 20% of pharmaceutical company respondents), and two in five biotech respondents (40%) select dispensing of drug product to clinicians as most challenging (compared to just 13% of those from pharmaceutical companies).

However, pharmaceutical company respondents are about twice as likely to track drug product by package bar code than are their counterparts in biotech (64% pharma, 33% biotech).

## Other Key Takeaways:

- The views of clinical directors and CRAs differ in a number of ways. For example, CRAs are about four times as likely to identify packaging as the most difficult aspect of the manufacturing and packaging process. CRAs are much more inclined to rate logistics costs and growth in emerging markets as significantly impactful. On the other hand, clinical directors are substantially more likely to view a greater need for accurate forecasting and an increased need for cold chain distribution as trends that will seriously influence how their companies will manage the clinical supply chain process.
- Companies are nearly twice as likely to face chronic (occurs more than five times a year) expiration of product or supply return issues than overage or stock out issues.
- Almost two-thirds of companies use temperature surveillance technological solutions in their cold chain management. One half of respondent companies use randomization and trial supply management (RTSM) solutions.
- Project management of manufacturing, identified by approximately one-third of respondents, is the most challenging aspect of manufacturing and packaging.
- The growth of biologics and vaccines is seen as the trend that has had the most impact on cold chain distribution.
- Half of respondent companies track drug product through package labels. Less than a third of them do so via product serialization.
- The administration of drugs to patients is seen as the most challenging aspect of site and patient management, with twice as many respondents selecting it over the dispensing of drug product to clinicians.