ThermoFisher SCIENTIFIC

COLD CHAIN INDUSTRY TRENDS

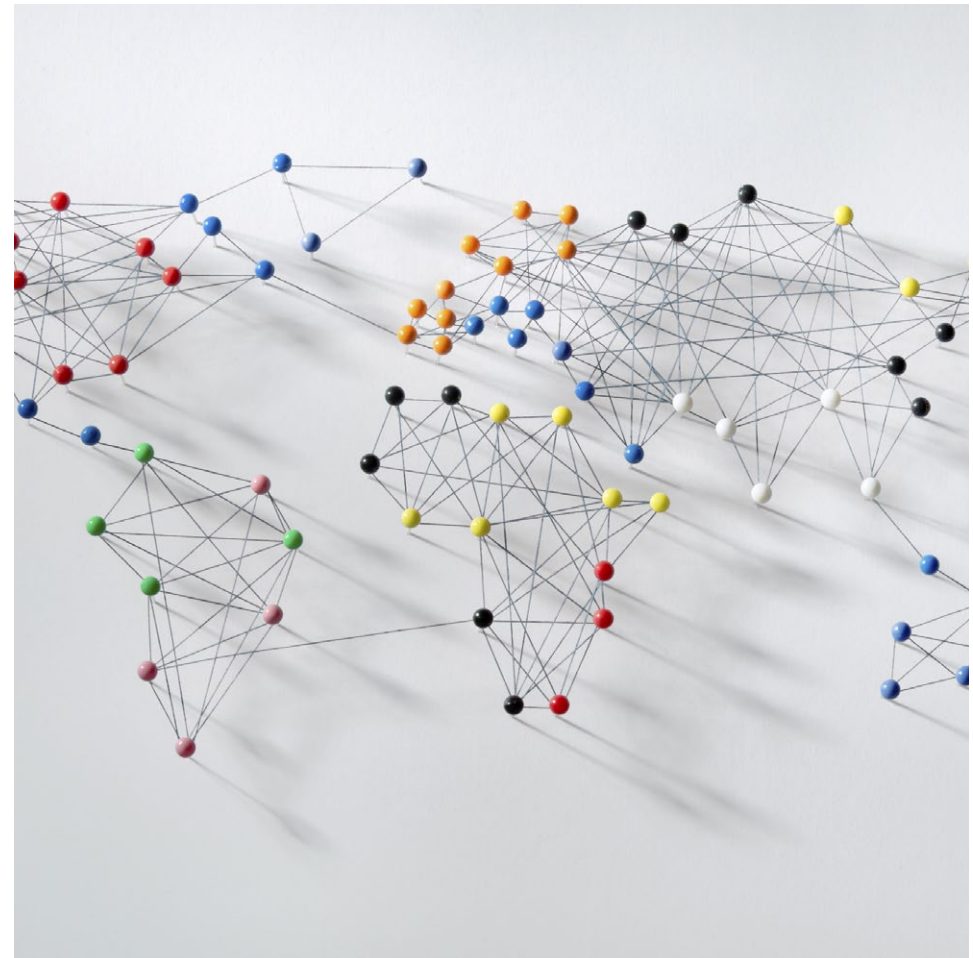
PLANNING TIPS TO CREATE A ROBUST SUPPLY CHAIN

patheon

- API
- BIOLOGICS
- VIRAL VECTOR SERVICES
- EARLY & LATE PHASE DEVELOPMENT
- **CLINICAL TRIAL SOLUTIONS**
- LOGISTICS SERVICES
- COMMERCIAL MANUFACTURING

Introduction and overview

The maintenance of cold chain product integrity across the entire supply chain demands rigorous processes and cold chain expertise of the highest calibre—from packaging, handling, storage & distribution of temperature sensitive Investigational Medicinal Products (IMP), all the way to the investigator site. These eBooks outline industry trends and reviews how Fisher Clinical Services solutions are meeting the challenges of the cold chain distribution of clinical trial supplies all over the world.



COLD CHAIN INDUSTRY TRENDS provides an industry overview and a framework for discussion. The importance of a robust supply chain is addressed. It includes planning recommendations for biopharmaceutical companies preparing to scale up to global vaccine trials.

COLD CHAIN SHIPPING CONSIDERATIONS takes a deep dive into passive shipping options and how they work, with information on the advantages and disadvantages of various coolants.

EVALUATING & QUALIFYING TEMPERATURE MANAGED SHIPPERS provides insight into how we qualify shipping options with a case study example of a 'return and reuse shipper pilot' which delivered very positive results.

MANAGING TEMPERATURE EXCURSIONS provides top tips on the best course of action to take, and provides summary recommendations for Sponsors on how to handle cold chain or temperature sensitive IMP across the supply chain, up until delivery to the investigator site.

Industry trends

‘Cold chain management’ is undoubtedly a hot topic in the clinical research industry because a rising percentage of the drugs in clinical testing today are biologics. The percentage of pharmaceuticals based on biologics and vaccines has grown tremendously in the past decade. With hundreds of vaccines in research and development worldwide, vaccines are among the fastest growing segments of the biopharmaceutical market today. In 2016, biologics accounted for six of the top-eight drugs, in terms of revenue. In fact, the global biologics market size is expected to reach around $319 billion by 2021 at an annual growth rate of 9.6%[2], more than twice the growth rate of conventional pharmaceuticals.

The interest in vaccines is fuelled by a variety of factors. Among them: the impact of globalisation, technological advances in biotechnology, post 9/11 concerns about biological warfare, the emergence and re-emergence of diseases such as Ebola, West Nile Virus and tuberculosis, and scientists’ pursuit of new vaccine targets such as cancer and Alzheimer’s disease. Another key contributor is the recognition by principal vaccine purchasers—healthcare providers and governments, whose ranks have swollen to include those of emerging markets such as China and India—of the ability of vaccines to reduce healthcare expenditures and increase quality of life through disease prevention.

New drug development is accompanied by formidable challenges, both for biopharmaceutical research companies pursuing the next generation of products, as well as the clinical supply chain partners. These partners often take responsibility for packaging, labeling, storing and delivering IMP for global clinical trials. In addition to their cost and complexity to develop and manufacture, vaccines must be stored, transported and maintained at controlled temperatures in a “cold chain environment.” Maintaining cold supply chain demands planning, partnering and attention to detail; a single broken link can result in loss of scarce resources and time, the twin currencies of the biopharmaceutical industry.

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1. BIOLOGICS MARKET - GROWTH, TRENDS, AND FORECAST (2019 - 2024). Report by Mordor Intelligence
2. Biologics Market By Types, By Trends, By Regions And By Key Players - Global Forecast To 2021 Report by The Business Research Company, March 2019

Planning in the early stages

As the volume of cold chain shipments has increased significantly year on year, the Fisher Clinical Services team has developed a proven model for use in crafting a robust cold supply chain. To begin at the outset—by thoroughly understanding the protocol and what the sponsor wishes to achieve—is critical.

PROTOCOL	PLANNING	PRODUCTIONS	DISTRIBUTION
Understand the protocol	Establish a budget (balance between cost and risk)	Make sure the kit fits easily into the site refrigerator	Ensure that enough depots and sub-depots are available
Understand what sponsors want	Anticipate and address requirements for customs and importation		
	Know when and how much vaccine will be available		
	Know the temperature requirements		

Planning in the early stages

Thorough understanding of the protocol enables us to craft a customized distribution strategy that addresses the following key issues:

Considerations for distribution

Facilities, depots & sub-depots

A sufficient number of facilities/depots and sub depots ensures that product is delivered to clinical sites as needed. Many prevalent diseases are in locations where there simply is no clinical trial infrastructure, the indigenous populations are travelling 100s of miles for any type of treatment and the planning of supply routes requires imagination and dedication.

Vaccine supply

Since vaccine is frequently in limited supply during early development, knowing when and how much product will be available is necessary for meeting tight clinical timelines

Kit size

An often overlooked and critical detail is the size of the kit, which must fit easily into the site refrigerators.

Temperature requirements

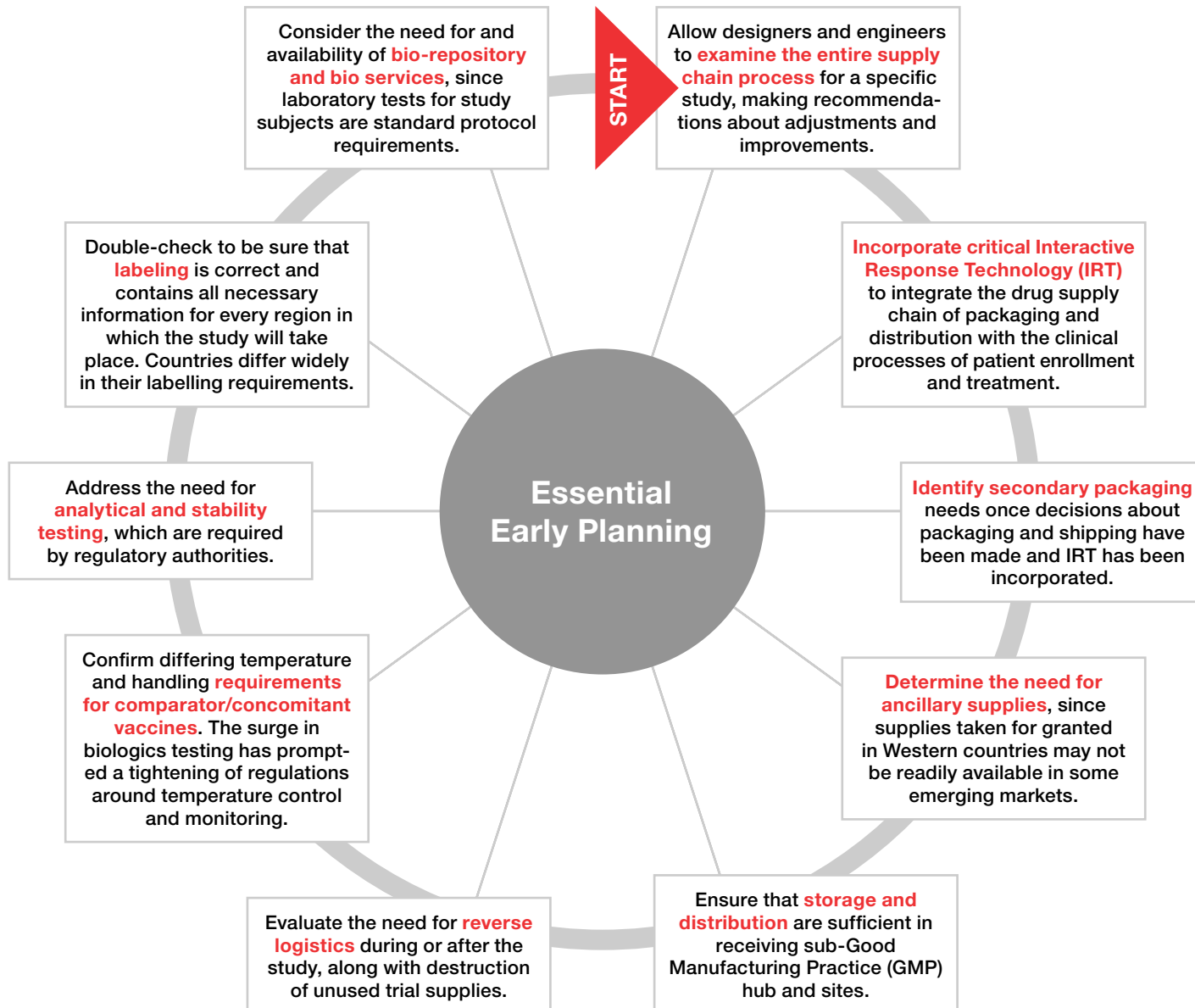
Temperature requirements impact the selection of appropriate packaging and monitoring, which ensure that product remains safe and efficacious.

Customs imports requirements

Requirements for customs and importation vary widely from country to country; anticipating and addressing them early in the process is critical. Customs delays as a result of documentation errors are commonplace and can lead to increased costs.

Strategy for a robust supply chain

Our strategy for establishing a robust refrigerated supply chain for clinical trials involves a rigorous process of proven durability. Ideally, planning should begin six to twelve months in advance of first patient enrollment, especially for vaccines when the trial needs to meet a specific window of infection. While clinical trial timelines sometimes get missed and the Fisher Clinical Services team can quickly accomodate change, advance planning is always preferred.



+1 919 226 3200 • thermofisher.com/patheon • pharmaservices@thermofisher.com

Published 09/21

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